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(54) **SURGICAL INSTRUMENTS**

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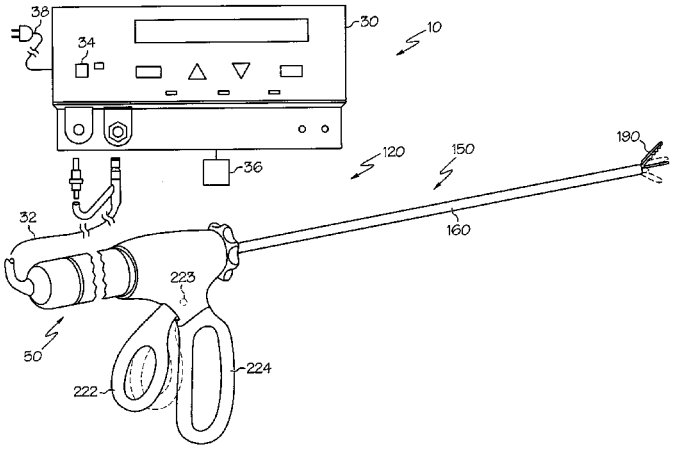
(57) **ABSTRACT**

A surgical device. The surgical device may comprise a transducer, an end effector, a generator and a control circuit. The transducer may be configured to provide vibrations. The end effector may be coupled to the transducer and may extend from the transducer along the longitudinal axis. The generator may provide an electrical signal to the transducer. Also, the control circuit may modify a current amplitude of the electrical signal in response to a change in a vibration frequency of the end effector. Accordingly to various embodiments, the control circuit may detect a first contribution to a vibration frequency of the end effector, the first contribution originating from tissue in contact with the end effector. Also, according to various embodiments, the control circuit may indicate a change in a vibration frequency of the end effector.

13 Claims, 18 Drawing Sheets



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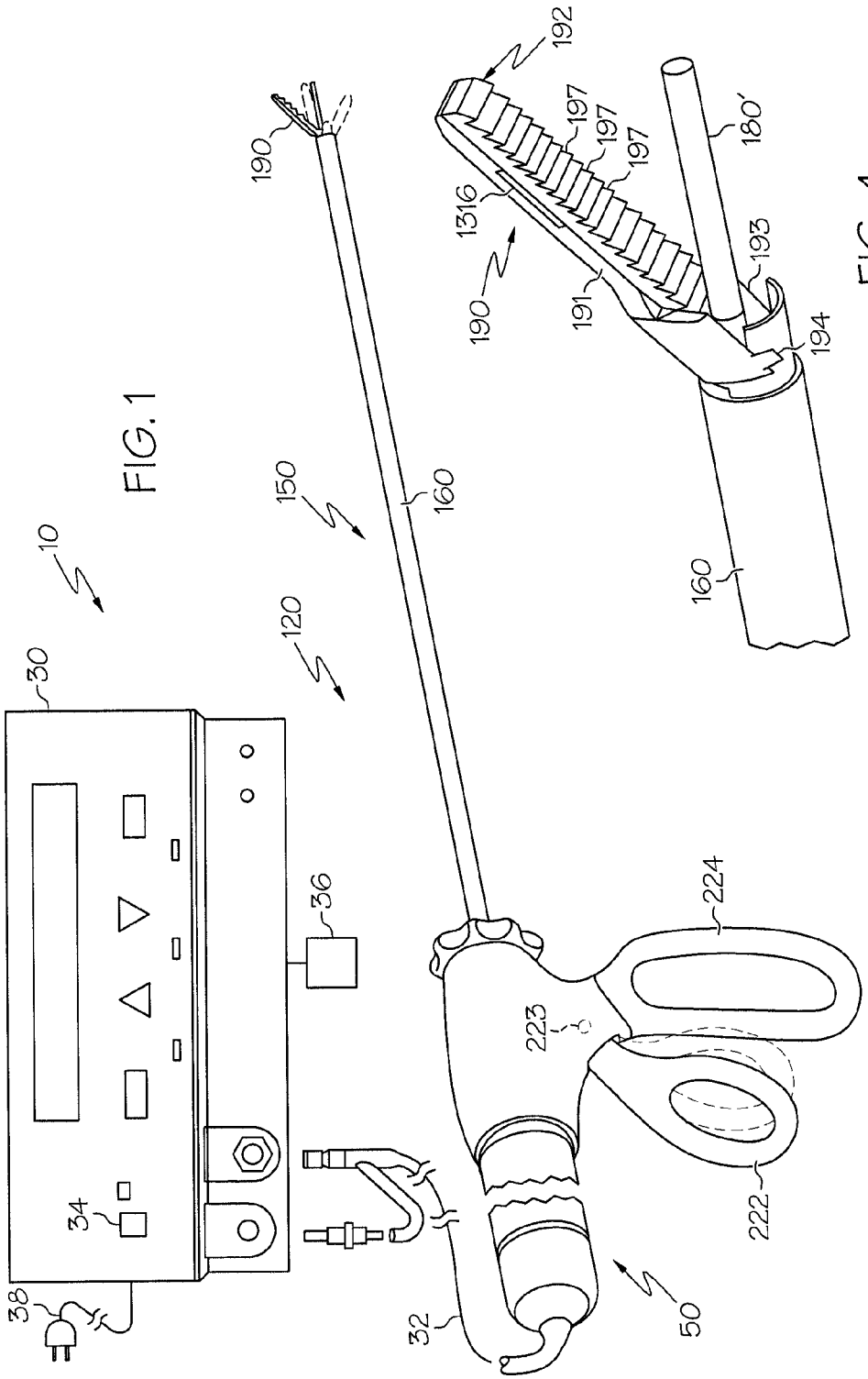
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FIG. 1

FIG. 4

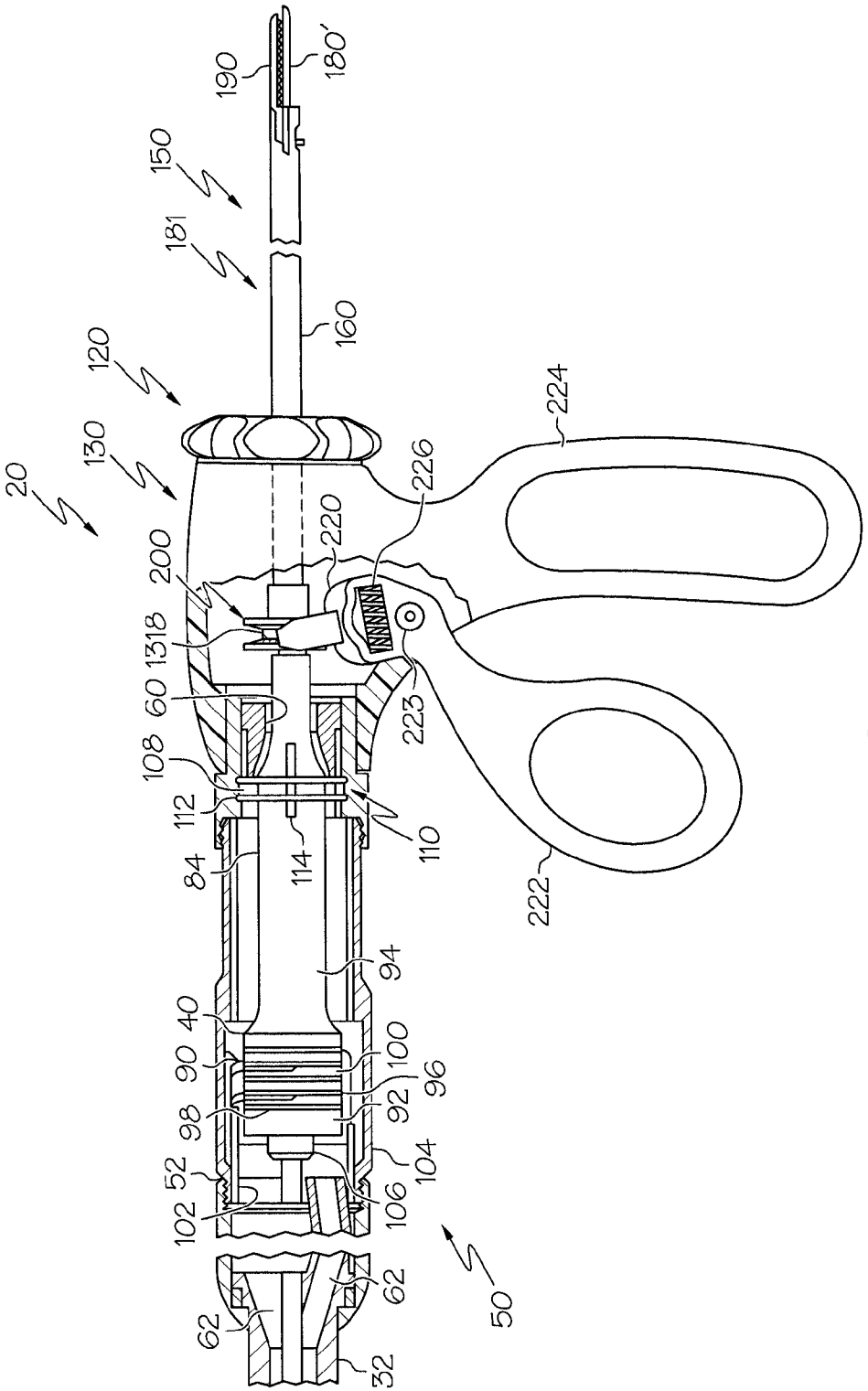
190
180'
150
181
160
120
130
20
224
226
220
200
1318
60
108
112
84
114
110
223
222
94
40
90
100
96
98
92
52
104
102
106
62
62
32
50

FIG. 2

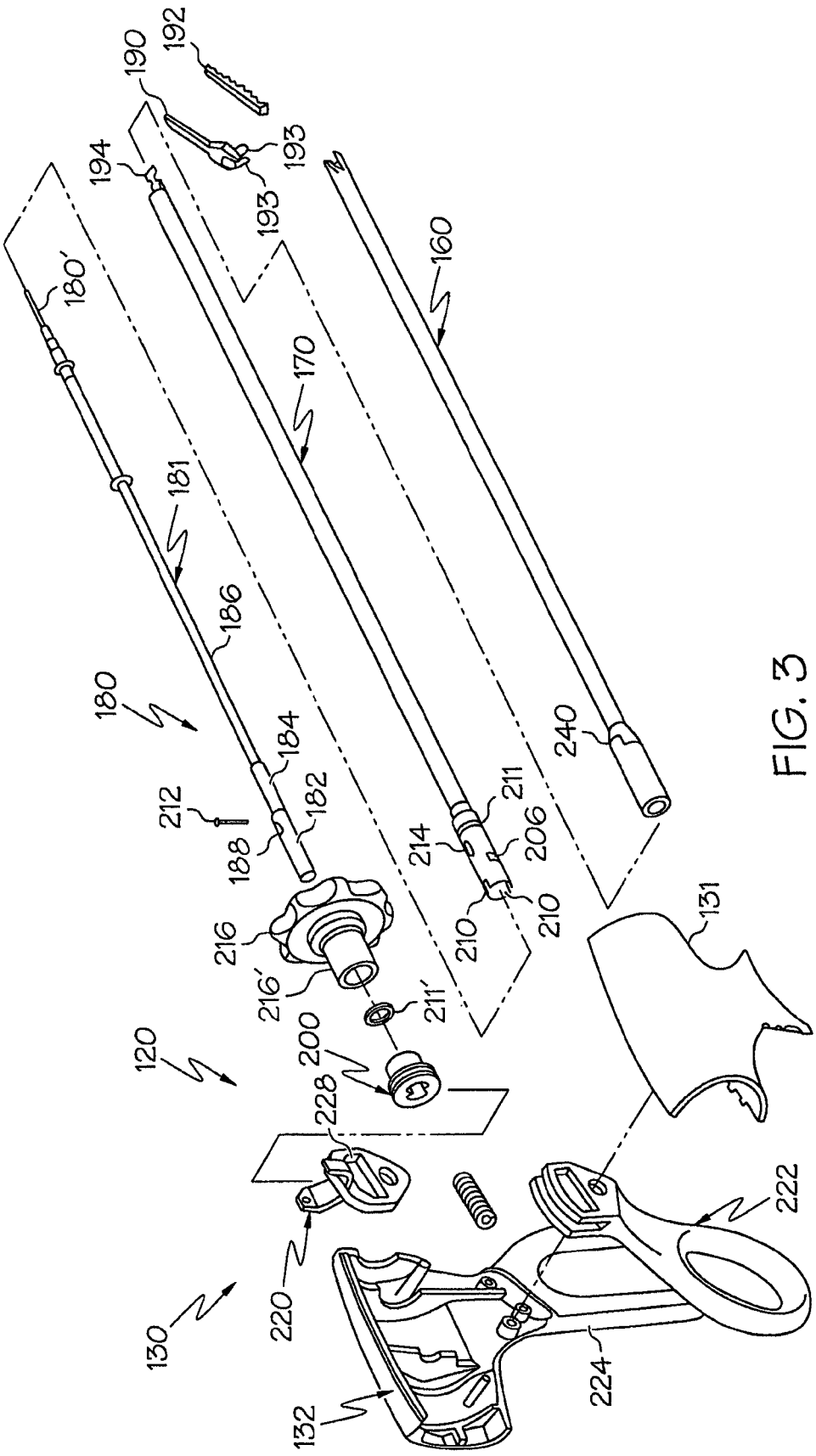
192
190
193
194
193
160
180'
170
181
186
180
184
182
212
188
211
214
206
210
210
240
216
216'
211'
131
120
200
228
222
220
130
224
132

FIG. 3

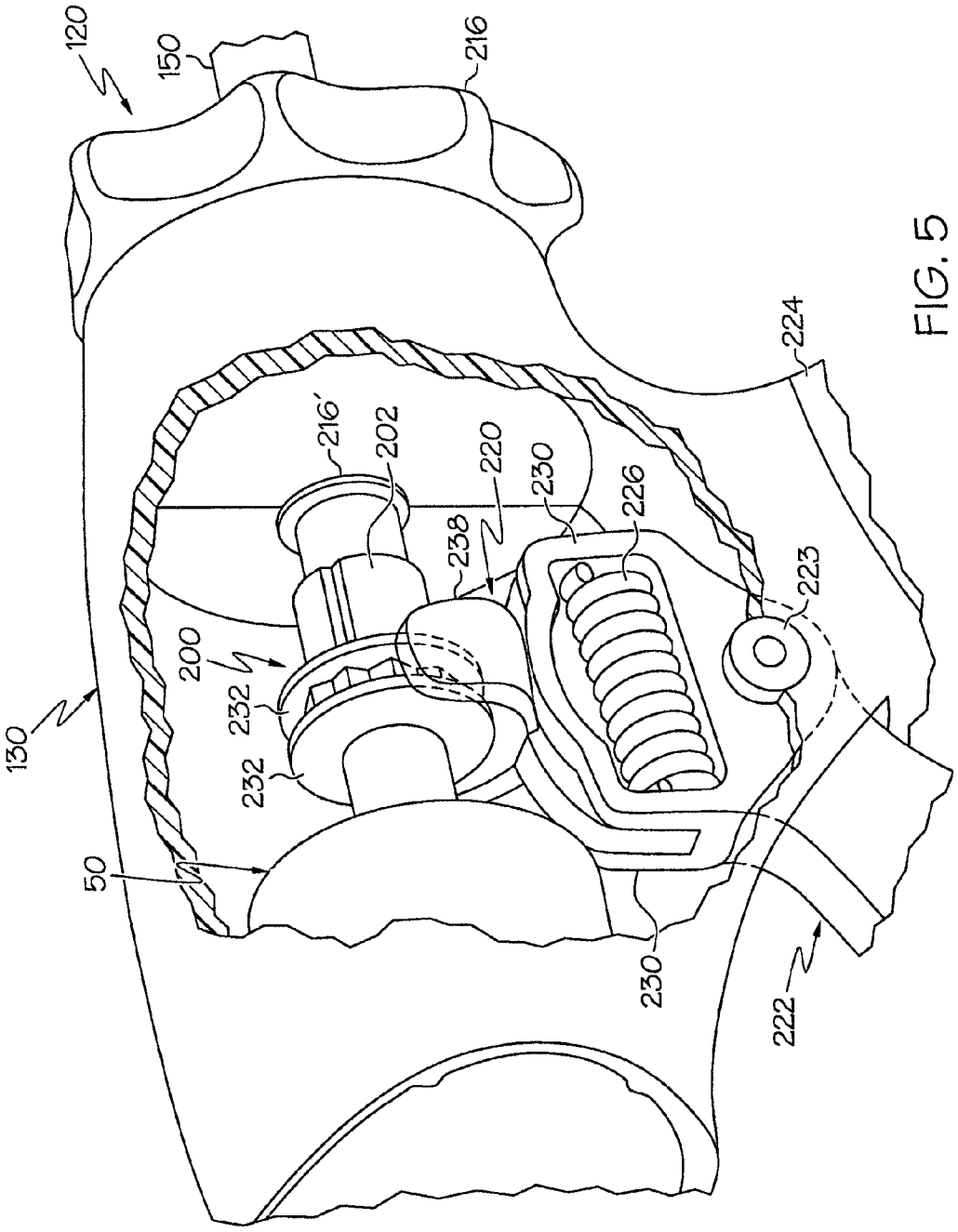
120
150
216
224
216'
202
220
230
226
238
223
200
232
232
130
50
230
222

FIG. 5

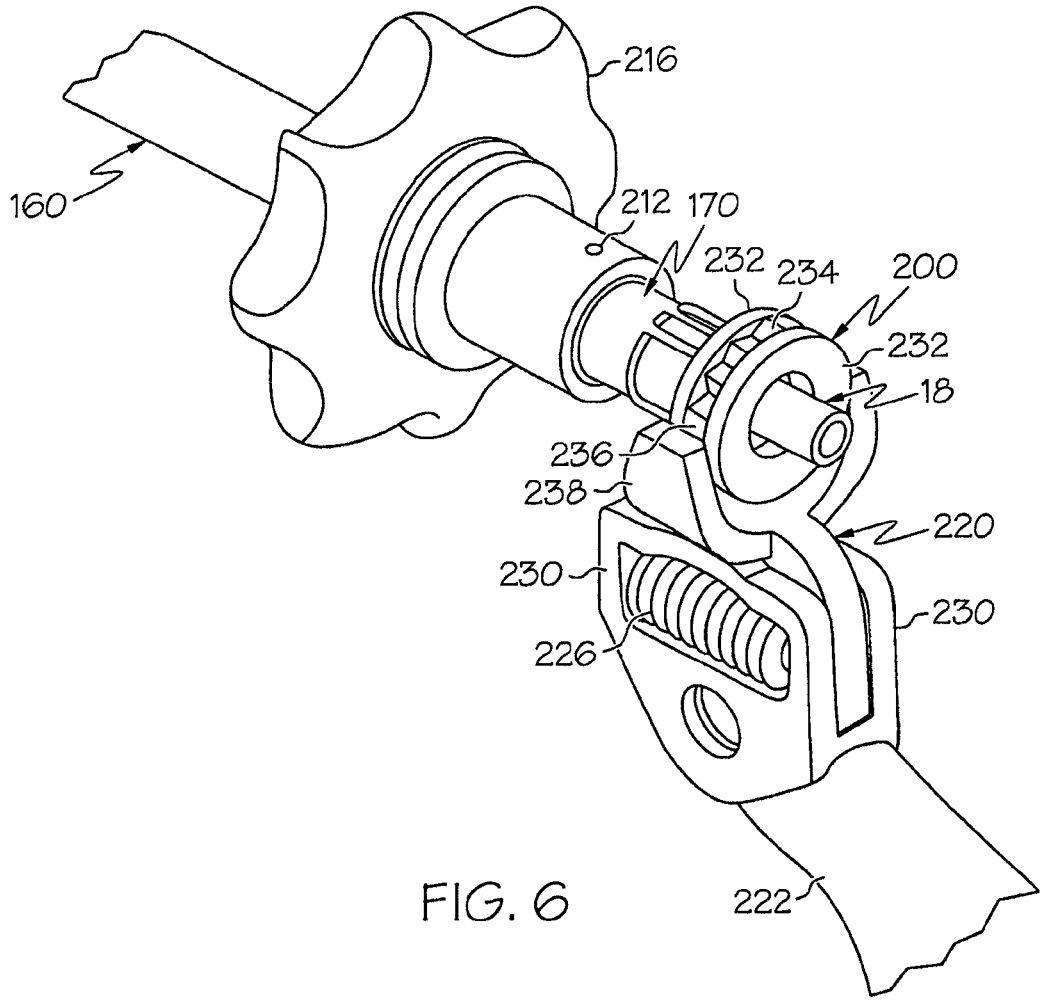

FIG. 6

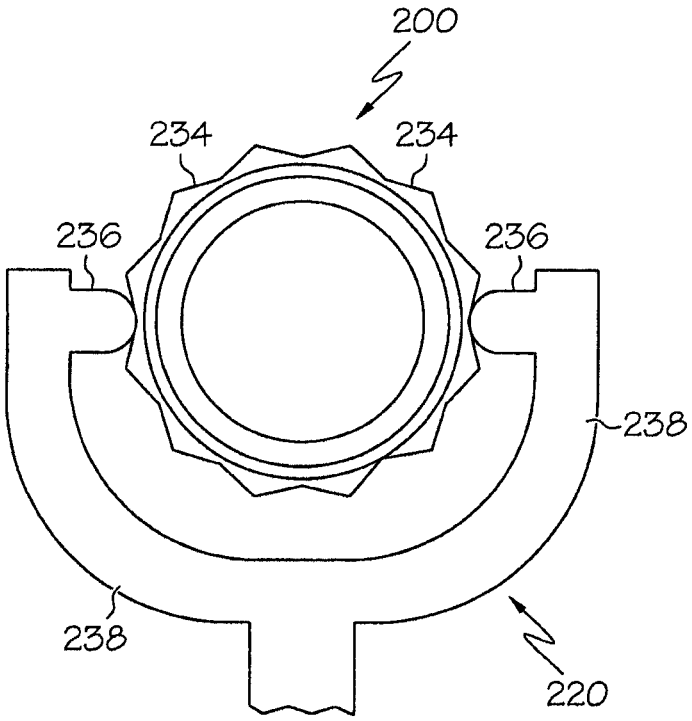
200
234
234
236
236
238
238
220

FIG. 7

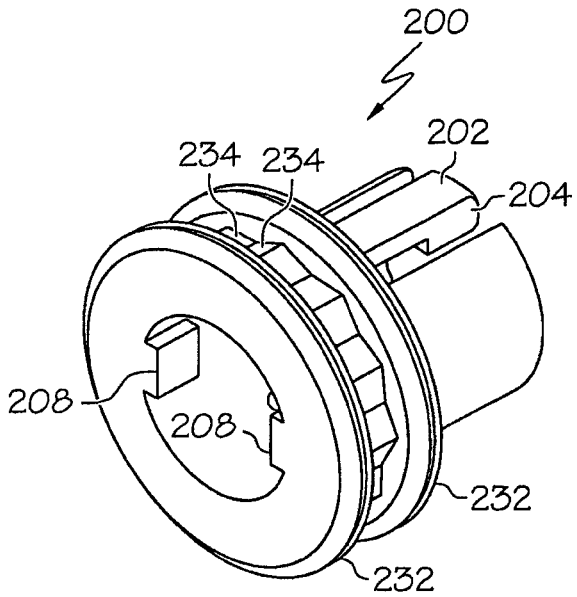
200
202
234
234
204
208
208
232
232

FIG. 8

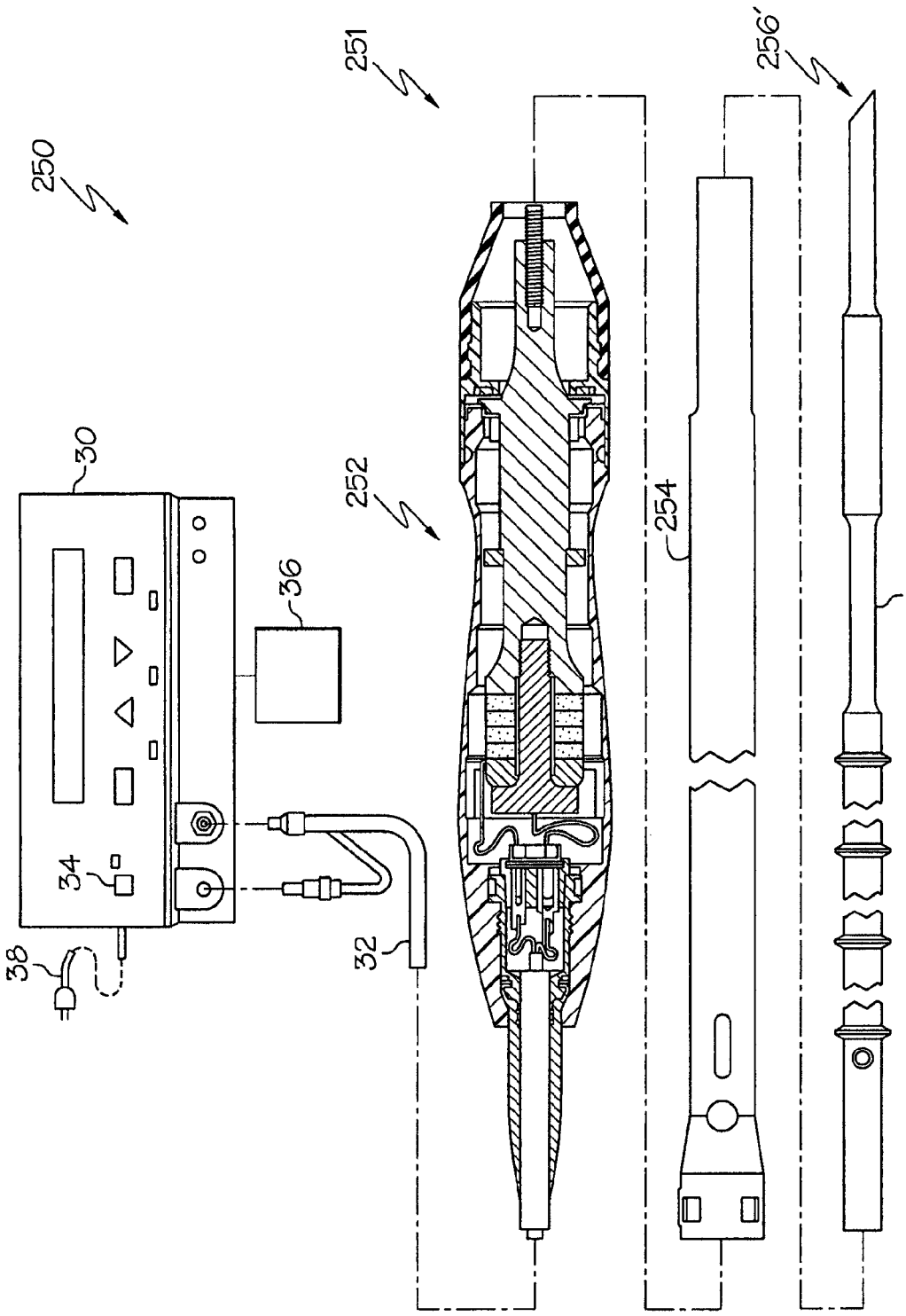

FIG. 9

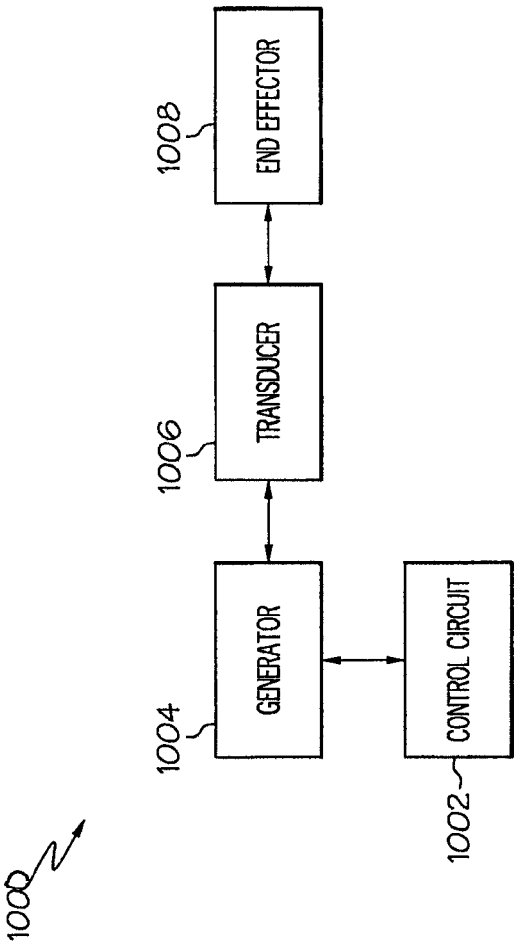
1000
1004
GENERATOR
1006
TRANSDUCER
1008
END EFFECTOR
1002
CONTROL CIRCUIT

FIG. 10

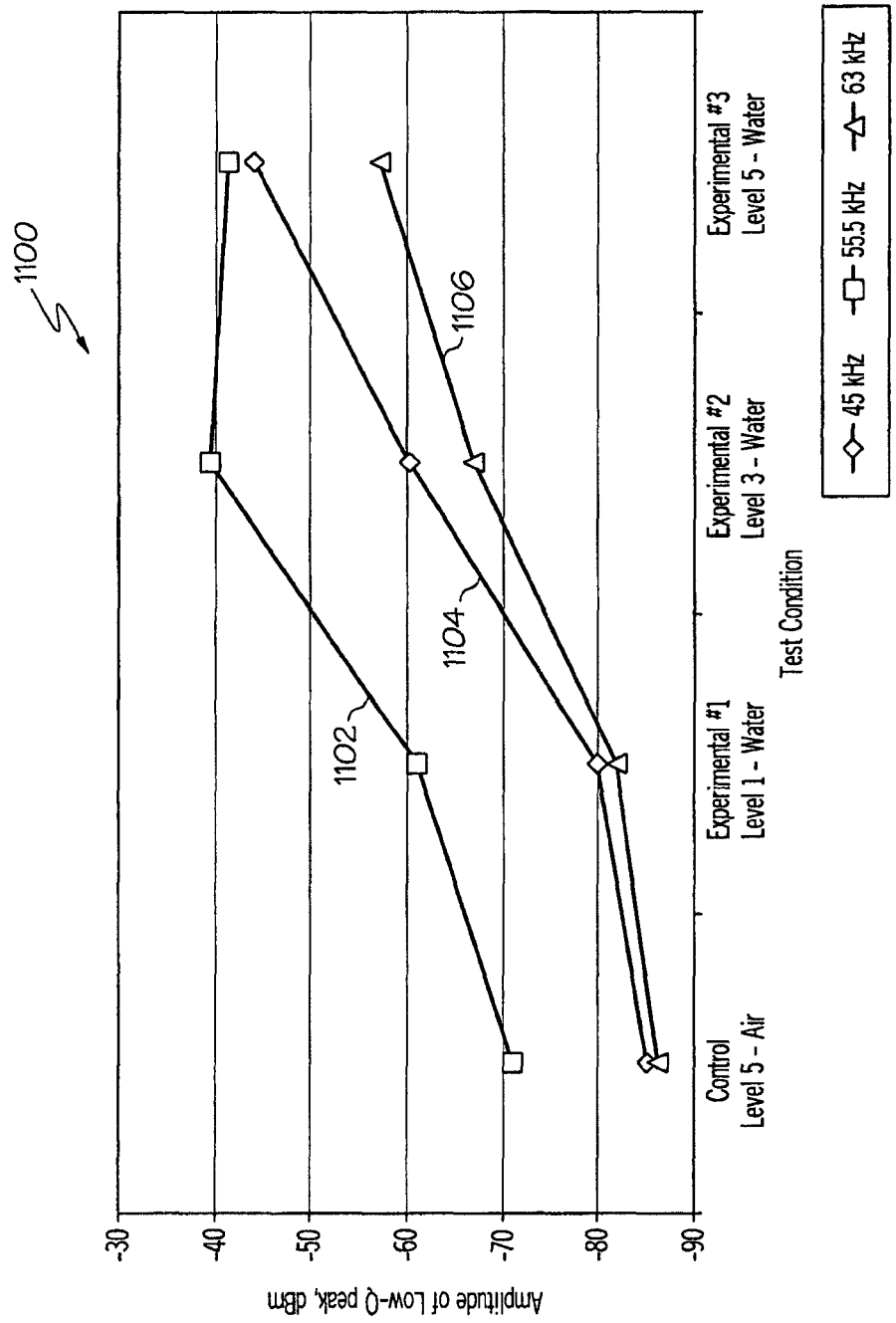
1100
1102
1104
1106
-30
-40
-50
-60
-70
-80
-90
Amplitude of Low-Q peak, dBm
Control
Level 5 - Air
Experimental #1
Level 1 - Water
Experimental #2
Level 3 - Water
Experimental #3
Level 5 - Water
Test Condition
45 kHz
55.5 kHz
63 kHz

FIG. 11

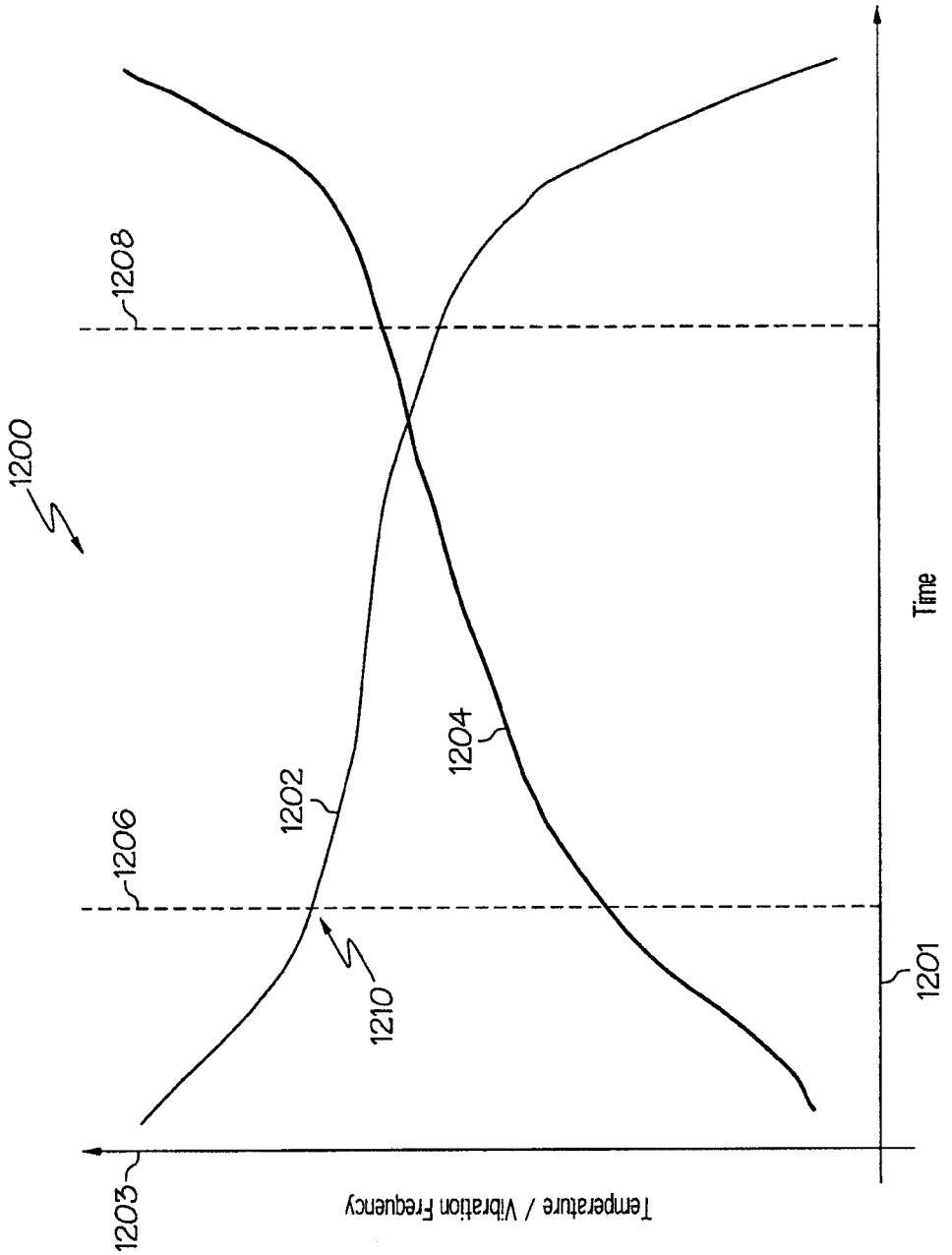
1200
1208
1206
1202
1204
1210
1201
1203
Time
Temperature / Vibration Frequency

FIG. 12

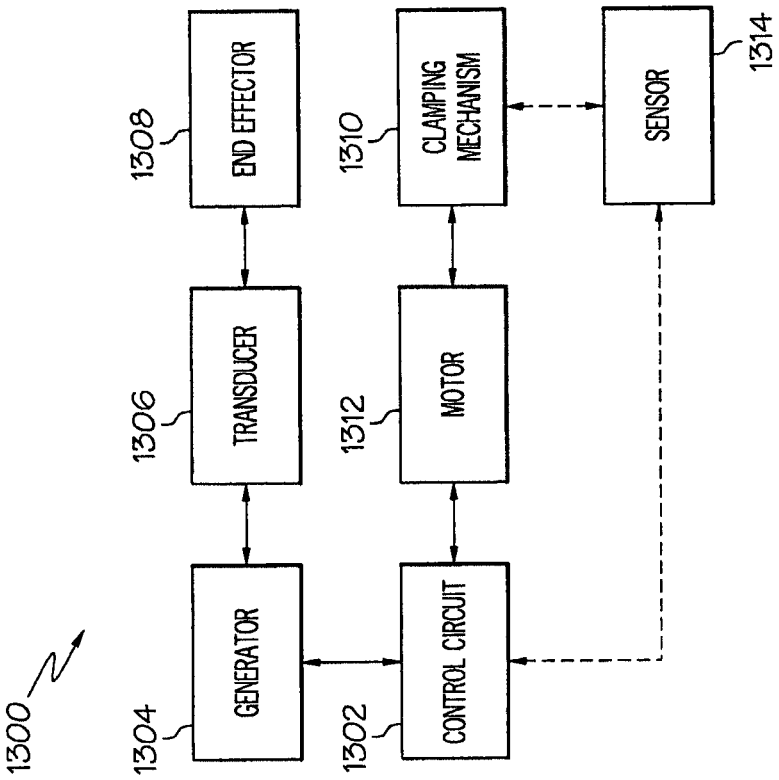
1300
1304
GENERATOR
1306
TRANSDUCER
1308
END EFFECTOR
1302
CONTROL CIRCUIT
1312
MOTOR
1310
CLAMPING MECHANISM
1314
SENSOR

FIG. 13

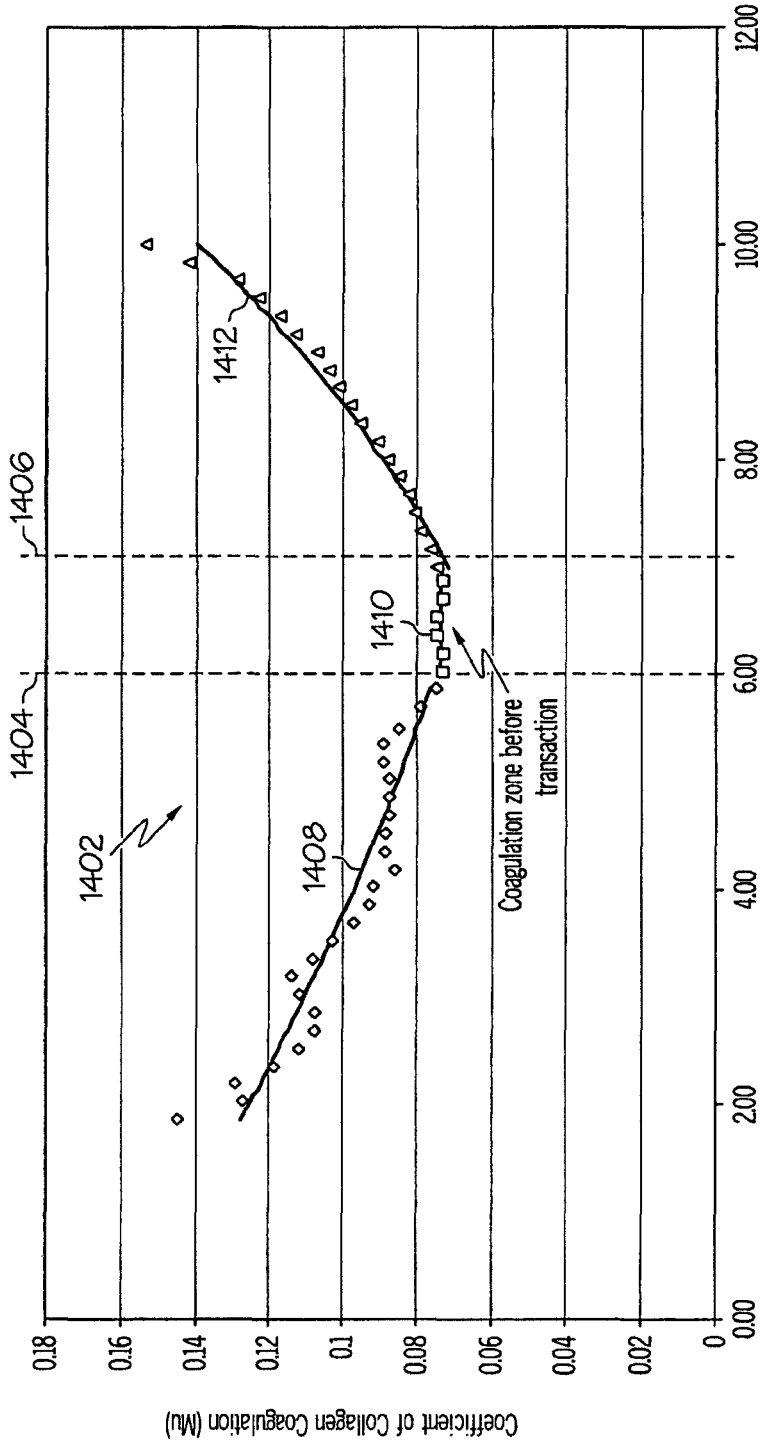
Coefficient of Collagen Coagulation (Mu)
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
0.00
2.00
4.00
6.00
8.00
10.00
12.00
Time (secs)
1402
1404
1406
1408
1410
1412
Coagulation zone before transaction

FIG. 14

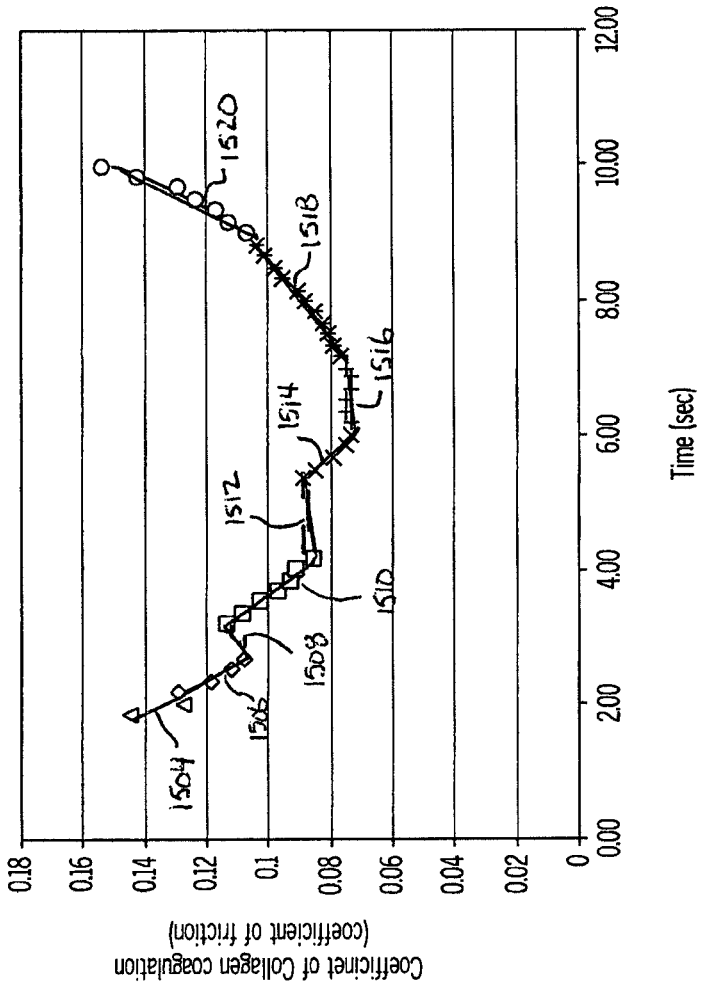
Coefficinet of Collagen coagulation
(coefficient of friction)
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
0.00
2.00
4.00
6.00
8.00
10.00
12.00
Time (sec)
1504
1506
1508
1510
1512
1514
1516
1518
1520

FIG. 15

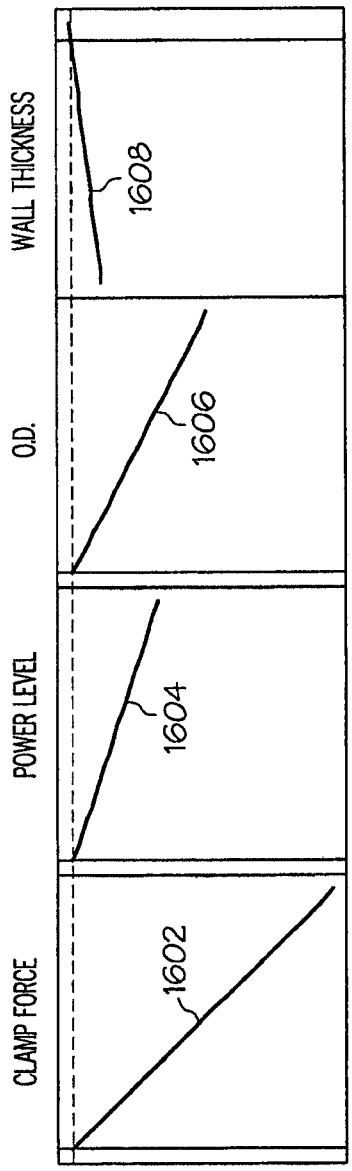
WALL THICKNESS
1608
O.D.
1606
POWER LEVEL
1604
CLAMP FORCE
1602

FIG. 16

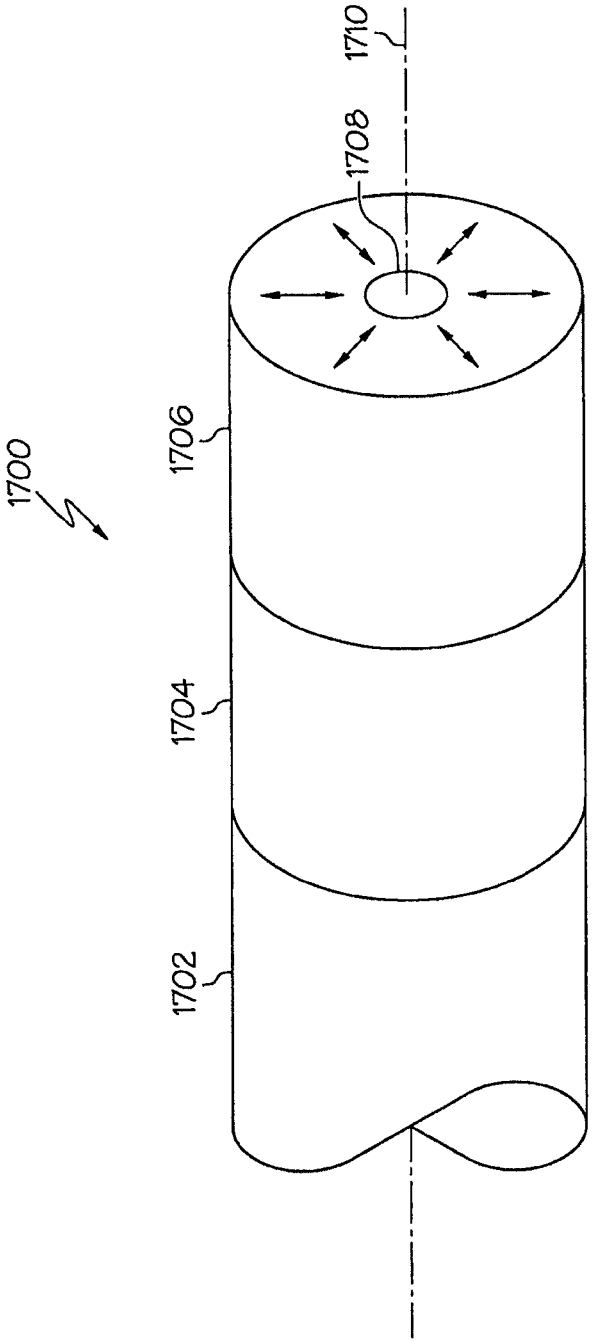

FIG. 17

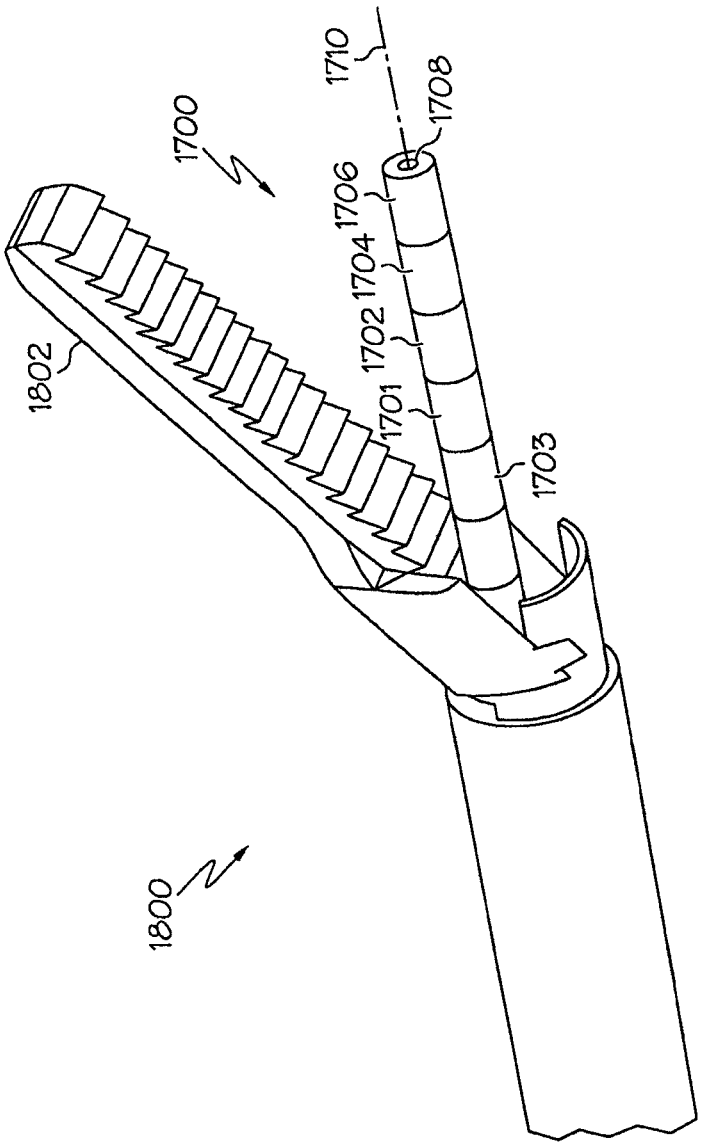

FIG. 18

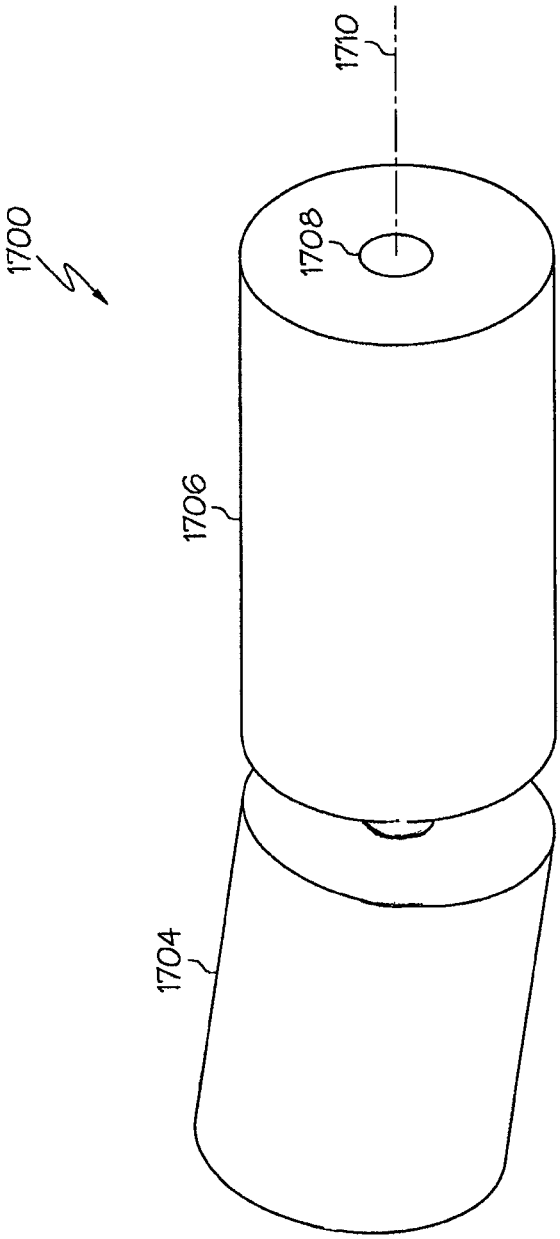

FIG. 19

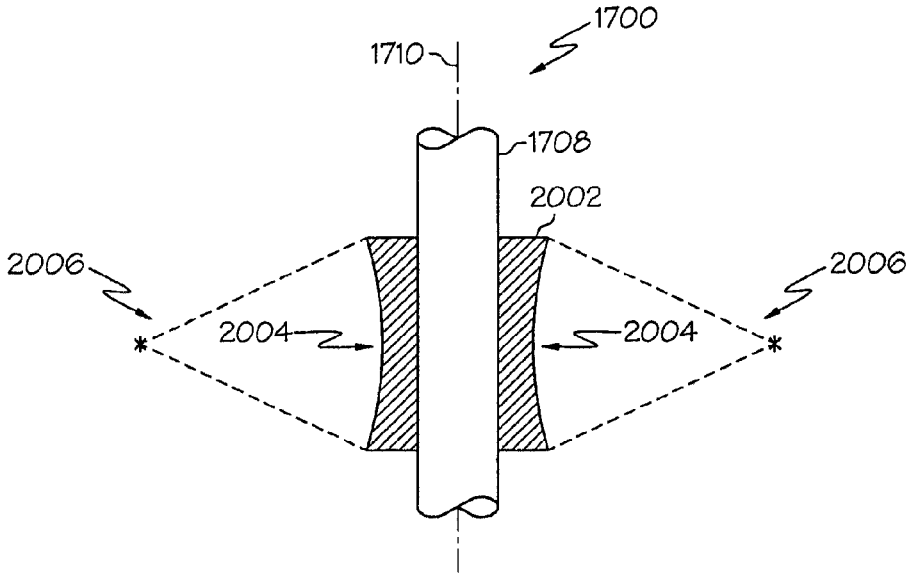
1700
1710
1708
2002
2006
2006
2004
2004

FIG. 20

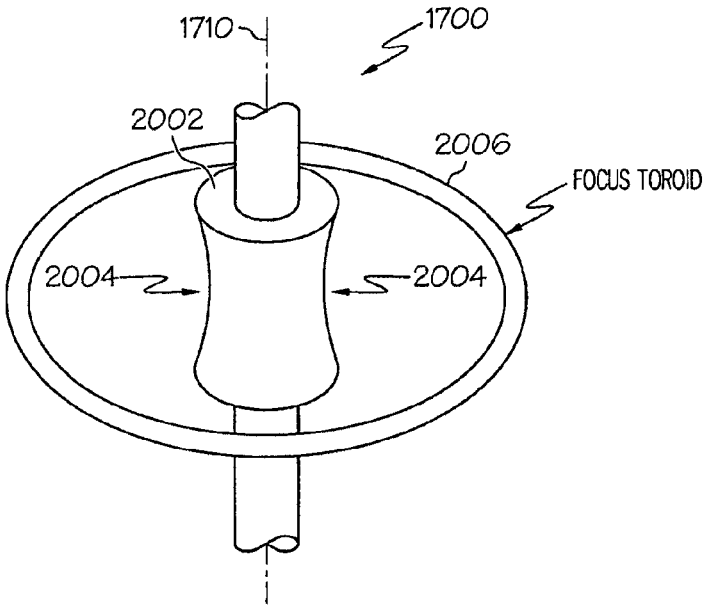
1710
1700
2002
2006
FOCUS TOROID
2004
2004

FIG. 21

SURGICAL INSTRUMENTS

The present application claims the benefit under at least 35 U.S.C. §120 as a continuation of U.S. patent application Ser. No. 11/888,222 filed on Jul. 31, 2007, now U.S. Patent Publication No. 2009/0036913, which is incorporated herein by reference in its entirety.

BACKGROUND

Ultrasonic instruments, including both hollow core and solid core instruments, are used for the safe and effective treatment of many medical conditions. Ultrasonic instruments are advantageous because they may be used to cut and/or coagulate organic tissue using energy in the form of mechanical vibrations transmitted to a surgical end effector at ultrasonic frequencies. Ultrasonic vibrations, when transmitted to organic tissue at suitable energy levels and using a suitable end effector, may be used to cut, dissect, elevate or cauterize tissue or to separate muscle tissue off bone. Such instruments may be used for open procedures or minimally invasive procedures, such as endoscopic or laparoscopic procedures, wherein the end effector is passed through a trocar to reach the surgical site.

Activating or exciting the end effector (e.g., cutting blade) of such instruments at ultrasonic frequencies induces longitudinal vibratory movement that generates localized heat within adjacent tissue, facilitating both cutting and coagulation. Because of the nature of ultrasonic instruments, a particular ultrasonically actuated end effector may be designed to perform numerous functions, including, for example, cutting and coagulation.

Ultrasonic vibration is induced in the surgical end effector by electrically exciting a transducer, for example. The transducer may be constructed of one or more piezoelectric or magnetostrictive elements in the instrument hand piece. Vibrations generated by the transducer section are transmitted to the surgical end effector via an ultrasonic waveguide extending from the transducer section to the surgical end effector. The waveguides and end effectors are designed to resonate at the same frequency as the transducer. Therefore, when an end effector is attached to a transducer the overall system frequency is the same frequency as the transducer itself.

The zero to peak amplitude of the longitudinal ultrasonic vibration at the tip, d, of the end effector behaves as a simple sinusoid at the resonant frequency as given by:

$$d=A\sin(\omega t)$$

where:

ω=the radian frequency which equals 2π times the cyclic frequency, f; and

A=the zero-to-peak amplitude.

The longitudinal excursion is defined as the peak-to-peak (p-t-p) amplitude, which is just twice the amplitude of the sine wave or 2A.

Ultrasonic surgical instruments may be divided into two types, single element end effector devices and multiple-element end effector devices. Single element end effector devices include instruments such as scalpels and ball coagulators. Single-element end effector instruments have limited ability to apply blade-to-tissue pressure when the tissue is soft and loosely supported. Sometimes, substantial pressure may be necessary to effectively couple ultrasonic energy to the tissue. This inability to grasp the tissue results in a further inability to fully coapt tissue surfaces while applying ultrasonic energy, leading to less-than-desired hemostasis and tissue joining. In these cases, multiple-element end effectors may be used. Multiple-element end effector devices, such as clamping coagulators, include a mechanism to press tissue against an ultrasonic blade that can overcome these deficiencies.

Although ultrasonic surgical instruments are widely used in many surgical applications, their utility is limited by their inability to react to tissue and end effector conditions. For example, as the end effector of an ultrasonic instrument is used to coagulate and/or cut tissue, it often heats up. This may cause inconsistencies in the performance of the instrument. Also, there is no way for a clinician using the instrument to know when the instrument has begun to coagulate tissue, when the instrument has begun to cut tissue, or any other information about the tissue.

Another set of drawbacks of ultrasonic instruments stems from existing end effector designs. In the existing designs, only the tip of the end effector (e.g., the blade) is ultrasonically active. Accordingly, tissue contacting the blade more than a fraction of a wavelength from the tip may not be affected at all. Further, because waves must propogate from the transducer to the tip of the end effector, existing end effectors are not very flexible, limiting their ability to articulate and consequently limiting their usefulness in laparoscopic and endoscopic surgical applications.

SUMMARY

In one general aspect, the various embodiments are directed to a surgical device. The surgical device may comprise a transducer, an end effector, a generator and a control circuit. The transducer may be configured to provide vibrations. The end effector may be coupled to the transducer and may extend from the transducer along the longitudinal axis. The generator may provide an electrical signal to the transducer. Also, the control circuit may modify a current amplitude of the electrical signal in response to a change in a vibration frequency of the end effector. Accordingly to various embodiments, the control circuit may detect a first contribution to a vibration frequency of the end effector, the first contribution originating from tissue in contact with the end effector. Also, according to various embodiments, the control circuit may indicate a change in a vibration frequency of the end effector.

In another general aspect, the various embodiments are directed to a surgical instrument comprising a transducer, a clamping mechanism and a control circuit. The transducer may be configured to provide vibrations. The end effector may be coupled to the transducer and may extend from the transducer along the longitudinal axis. The clamping mechanism may be translatable toward the end effector. The control circuit may calculate a curve representing a coefficient of collagen denaturation over time. The coefficient of collagen denaturation may be calculated considering: a power delivered by the end effector to a portion of tissue; a clamp force applied to the portion of tissue between the end effector and the clamping mechanism; a displacement of the end effector; and a vibration frequency of the end effector. According to various embodiments, the control circuit also may identify a first change in a slope of the curve from a substantially negative slope to a substantially neutral slope and indicate a beginning of tissue coagulation in response to the first change. Also, according to various embodiments, the control circuit may identify a first region of the curve having a substantially constant slope. The control circuit

also may calculate a region property describing the first region and derive a tissue property of the portion of tissue in contact with the end effector.

In yet another general aspect, the various embodiments are directed to a surgical device comprising an end effector. The end effector may comprise a central member extending longitudinally through the end effector and a plurality of radial mode transducers. The radial mode transducers may be positioned around the central member, and may be configured to respond to an electrical signal by vibrating in a direction perpendicular to the longitudinal axis. The standing waves may be ultrasonic.

FIGURES

The novel features of the various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, together with further objects and advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings as follows.

FIG. **1** illustrates one embodiment of a surgical system including a surgical instrument and an ultrasonic generator.

FIG. **2** illustrates one embodiment of the surgical instrument shown in FIG. **1**.

FIG. **3** illustrates an exploded view of one embodiment the surgical instrument shown in FIG. **1**.

FIG. **4** illustrates one embodiment of a clamping mechanism that may be used with the surgical instrument shown in FIG. **1**.

FIG. **5** illustrates a cut-away view of one embodiment of the surgical instrument shown in FIG. **1**.

FIG. **6** illustrates various internal components of one embodiment of the surgical instrument shown in FIG. **1**.

FIG. **7** illustrates one embodiment of a drive yoke of the surgical instrument shown in FIG. **1**.

FIG. **8** illustrates one embodiment of a drive collar of the surgical instrument shown in FIG. **1**.

FIG. **9** illustrates one embodiment of a surgical system including a surgical instrument having single element end effector.

FIG. **10** illustrates a block diagram of one embodiment of a surgical device.

FIG. **11** shows a graph illustrating results of an example test of a surgical device.

FIG. **12** shows a graph illustrating a relationship between end effector frequency and end effector temperature.

FIG. **13** illustrates a block diagram of one embodiment of a surgical device.

FIG. **14** shows a graph illustrating a coefficient of collagen denaturation curve.

FIG. **15** shows a graph illustrating a coefficient of collagen denaturation curve.

FIG. **16** shows a series of curves illustrating relationships between a normalized value of a first region of a coefficient of collagen denaturation curve and clamp force, power level, outside diameter and wall thickness.

FIG. **17** illustrates one embodiment of an end effector for a surgical device including radial mode transducers.

FIG. **18** illustrates one embodiment of the end effector of FIG. **17** installed on a surgical instrument including a clamp arm.

FIG. **19** illustrates one embodiment of the end effector of FIG. **17** including a flexible central member.

FIG. **20** illustrates one embodiment of the end effector of FIG. **17** including a transducer defining a concavity.

FIG. **21** illustrates one embodiment of the end effector of FIG. **20**.

DESCRIPTION

Before explaining the various embodiments in detail, it should be noted that the embodiments are not limited in application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description. The illustrative embodiments may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. For example, the surgical instruments and blade configurations disclosed below are illustrative only and not meant to limit the scope or application thereof. Also, the blade and end effector designs described hereinbelow may be used in conjunction with any suitable device. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments for the convenience of the reader and are not to limit the scope thereof.

Examples of ultrasonic surgical instruments and blades are disclosed in U.S. Pat. Nos. 5,322,055 and 5,954,736, 6,309,400 B2, 6,278,218B1, 6,283,981 B1, and 6,325,811 B1, which are incorporated herein by reference in their entirety. These references disclose ultrasonic surgical instrument designs and blade designs where a longitudinal mode of the blade is excited. The result is a longitudinal standing wave within the instrument. Accordingly, the instrument has nodes, where the transverse motion is equal to zero, and anti-nodes, where the transverse motion is at its maximum. The instrument's tissue end effector is often positioned at an anti-node to maximize its longitudinal motion.

Various embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting embodiments and that the scope of the various embodiments is defined solely by the claims. The features illustrated or described in connection with one embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the claims.

It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician gripping a surgical device at its hand piece assembly, or other comparable piece. Thus, the end effector is distal with respect to the more proximal hand piece assembly. It will be further appreciated that, for convenience and clarity, spatial terms such as "top" and "bottom" also are used herein with respect to the clinician gripping the hand piece assembly, or comparable piece. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

FIG. **1** illustrates one embodiment of a surgical system including a surgical instrument and an ultrasonic generator. FIG. **2** illustrates one embodiment of the apparatus shown in FIG. **1**. In the embodiment illustrated in FIGS. **1-2**, the surgical system **10** includes an ultrasonic clamp coagulator instrument **120** and an ultrasonic generator **30**. The surgical instrument **120** includes an ultrasonic drive unit **50**. As will be further described, an ultrasonic transducer of the drive unit **50**, and an ultrasonic end effector **180** of the clamp

instrument **120**, together provide an acoustic assembly of the surgical system **10**, with the acoustic assembly providing ultrasonic energy for surgical procedures when powered by generator **30**. It will be noted that, in some applications, the ultrasonic drive unit **50** is referred to as a "hand piece assembly" because the surgical instrument **120** of the surgical system **10** is configured such that a clinician grasps and manipulates the ultrasonic drive unit **50** during various procedures and operations. The instrument **120** may include a scissors-like grip arrangement which facilitates positioning and manipulation of the instrument **120** apart from manipulation of the ultrasonic drive unit **50**.

The generator **30** of the surgical system **10** sends an electrical signal through a cable **32** at a selected excursion, frequency, and phase determined by a control system of the generator **30**. As will be further described, the signal causes one or more piezoelectric elements of the acoustic assembly of the surgical instrument **120** to expand and contract along a longitudinal axis, thereby converting the electrical energy into mechanical motion. The mechanical motion results in longitudinal waves of ultrasonic energy that propagate through the acoustic assembly in an acoustic standing wave to vibrate the acoustic assembly at a selected frequency and excursion. The end effector **180** is placed in contact with tissue of the patient to transfer the ultrasonic energy to the tissue. For example, a distal portion of blade **180'** of the end effector may be placed in contact with the tissue. As further described below, a surgical tool, such as, a jaw or clamping mechanism, may be utilized to press the tissue against the blade **180'**.

As the end effector **180** couples with the tissue, thermal energy or heat is generated as a result of friction, acoustic absorption, and viscous losses within the tissue. The heat is sufficient to break protein hydrogen bonds, causing the highly structured protein (e.g., collagen and muscle protein) to denature (e.g., become less organized). As the proteins are denatured, a sticky coagulum forms to seal or coagulate small blood vessels. Deep coagulation of larger blood vessels results when the effect is prolonged.

The transfer of the ultrasonic energy to the tissue causes other effects including mechanical tearing, cutting, cavitation, cell disruption, and emulsification. The amount of cutting as well as the degree of coagulation obtained varies with the excursion of the end effector **180**, the frequency of vibration, the amount of pressure applied by the user, the sharpness of the end effector **180**, and the coupling between the end effector **180** and the tissue.

In the embodiment illustrated in FIG. **1**, the generator **30** includes a control system integral with the generator **30**, a power switch **34**, and a triggering mechanism **36**. The power switch **34** controls the electrical power to the generator **30**, and when activated by the triggering mechanism **36**, the generator **30** provides energy to drive the acoustic assembly of the surgical system **10** frequency and to drive the end effector **180** at a predetermined excursion level. The generator **30** drives or excites the acoustic assembly at any suitable resonant frequency of the acoustic assembly.

When the generator **30** is activated via the triggering mechanism **36**, electrical energy is continuously applied by the generator **30** to a transducer stack or assembly **40** of the acoustic assembly. A phase-locked loop in the control system of the generator **30** monitors feedback from the acoustic assembly. The phase lock loop adjusts the frequency of the electrical energy sent by the generator **30** to match the resonant frequency of the selected longitudinal mode of vibration of the acoustic assembly. In addition, a second feedback loop in the control system maintains the electrical current supplied to the acoustic assembly at a pre-selected constant level in order to achieve substantially constant excursion at the end effector **180** of the acoustic assembly.

The electrical signal supplied to the acoustic assembly will cause the distal end of the end effector **180**, e.g., the blade **180'**, to vibrate longitudinally in the range of, for example, approximately 20 kHz to 250 kHz. According to various embodiments, the blade **180'** may vibrate in the range of about 54 kHz to 56 kHz, for example, at about 55.5 kHz. In other embodiments, the blade **180'** may vibrate at other frequencies including, for example, about 31 kHz or about 80 kHz. The excursion of the vibrations at the blade can be controlled by, for example, controlling the amplitude of the electrical signal applied to the transducer assembly **40** of the acoustic assembly by the generator **30**.

As noted above, the triggering mechanism **36** of the generator **30** allows a user to activate the generator **30** so that electrical energy may be continuously supplied to the acoustic assembly. The triggering mechanism **36** may comprise a foot activating switch that is detachably coupled or attached to the generator **30** by a cable or cord. Alternatively, the triggering mechanism can be configured as a hand switch incorporated in the ultrasonic drive unit **50** to allow the generator **30** to be activated by a user.

The generator **30** also has a power line **38** for insertion in an electro-surgical unit or conventional electrical outlet. It is contemplated that the generator **30** can also be powered by a direct current (DC) source, such as a battery. The generator **30** can comprise any suitable generator, such as Model No. GEN04, available from Ethicon Endo Surgery, Inc.

In the embodiment illustrated in FIGS. **1** and **3**, the ultrasonic drive unit **50** of the surgical instrument includes a multi-piece housing **52** adapted to isolate the operator from the vibrations of the acoustic assembly. The drive unit housing **52** can be shaped to be held by a user in a conventional manner, but it is contemplated that the present clamp coagulator instrument **120** principally be grasped and manipulated by a scissors-like arrangement provided by a housing of the apparatus, as will be described. While the multi-piece housing **52** is illustrated, the housing **52** may comprise a single or unitary component.

The housing **52** of the ultrasonic drive unit **50** generally includes a proximal end, a distal end, and a cavity extending longitudinally therein. The distal end of the housing **52** includes an opening **60** configured to allow the acoustic assembly of the surgical system **10** to extend therethrough, and the proximal end of the housing **52** is coupled to the generator **30** by the cable **32**. The cable **32** may include ducts or vents **62** to allow air or other fluids to be introduced into the housing **52** of the ultrasonic drive unit **50** to cool the transducer assembly **40** of the acoustic assembly.

The housing **52** of the ultrasonic drive unit **50** may be constructed from a durable plastic, such as ULTEM®. It is also contemplated that the housing **52** may alternatively be made from a variety of materials including other plastics (e.g. liquid crystal polymer (LCP), nylon, or polycarbonate) and/or metals (e.g., aluminum, steel, etc.). A suitable ultrasonic drive unit **50** is Model No. HP054, available from Ethicon Endo Surgery, Inc.

The acoustic assembly of the surgical instrument generally includes a first acoustic portion and a second acoustic portion. The first acoustic portion may be carried by the ultrasonic drive unit **50**, and the second acoustic portion (in the form of an end effector **180**, as will be described) is carried by the ultrasonic clamp coagulator **120**. The distal

end of the first acoustic portion is operatively coupled to the proximal end of the second acoustic portion, preferably by a threaded connection.

In the embodiment illustrated in FIG. **2**, the first acoustic portion includes the transducer stack or assembly **40** and a mounting device **84**, and the second acoustic portion includes the end effector **180**. The end effector **180** may in turn comprise a transmission component, or waveguide **181** (FIG. **3**), as well as a distal portion, or blade **180'**, for interfacing with tissue.

The components of the acoustic assembly may be acoustically tuned such that the length of each component is an integral number of one-half wavelengths ($n\lambda/2$), where the wavelength λ is the wavelength of a pre-selected or operating longitudinal vibration frequency f_0 of the acoustic assembly, and n is any non-negative integer. It is also contemplated that the acoustic assembly may incorporate any suitable arrangement of acoustic elements.

The transducer assembly **40** of the acoustic assembly converts the electrical signal from the generator **30** into mechanical energy that results in longitudinal vibratory motion of the end effector **180** at ultrasonic frequencies. When the acoustic assembly is energized, a vibratory motion standing wave is generated through the acoustic assembly. The excursion of the vibratory motion at any point along the acoustic assembly depends on the location along the acoustic assembly at which the vibratory motion is measured. A minimum or zero crossing in the vibratory motion standing wave is generally referred to as a node (e.g., where motion is usually minimal), and local absolute value maximum or peak in the standing wave is generally referred to as an anti-node. The distance between an anti-node and its nearest node is one-quarter wavelength ($\lambda/4$).

In the embodiment illustrated in FIG. **2**, the transducer assembly **40** of the acoustic assembly, which is also known as a "Langevin stack", generally includes a transduction portion **90**, a first resonator **92**, and a second resonator **94**. The transducer assembly **40** may be an integral number of one-half system wavelengths ($n\lambda/2$) in length. It is to be understood that other embodiments of the transducer assembly **40** may comprise a magnetostrictive, electromagnetic or electrostatic transducer.

The distal end of the first resonator **92** is connected to the proximal end of transduction section **90**, and the proximal end of the second resonator **94** is connected to the distal end of transduction portion **90**. The first and second resonators **92** and **94** may be fabricated from titanium, aluminum, steel, or any other suitable material, and most preferably, the first resonator **92** is fabricated from 303 stainless steel and the second resonator **94** is fabricated from 7075-T651 Aluminum. The first and second resonators **92** and **94** have a length determined by a number of variables, including the length of the transduction section **90**, the speed of sound of material used in the resonators **92** and **94**, and the desired fundamental frequency f_0 of the transducer assembly **40**. The second resonator **94** can be tapered inwardly from its proximal end to its distal end to function as a velocity transformer and amplify the ultrasonic vibration excursion.

The transduction portion **90** of the transducer assembly **40** may comprise a piezoelectric section of alternating positive electrodes **96** and negative electrodes **98**, with the piezoelectric elements **100** alternating between the electrodes **96** and **98**. The piezoelectric elements **100** can be fabricated from any suitable material, such as, for example, lead zirconate-titanate, lead metaniobate, lead titanate, or other piezoelectric material. Each of the positive electrodes **96**, negative electrodes **98**, and piezoelectric elements **100** have a bore extending through the center. The positive and negative electrodes **96** and **98** are electrically coupled to wires **102** and **104**, respectfully. The wires **102** and **104** transmit the electrical signal from the generator **30** to the electrodes **96** and **98**.

The piezoelectric elements **100** may be held in compression between the first and second resonators **92** and **94** by a bolt **106**. The bolt **106** may have a head, a shank, and a threaded distal end. The bolt **106** may be inserted from the proximal end of the first resonator **92** through the bores of the first resonator **92**, the electrodes **96** and **98**, and piezoelectric elements **100**. The threaded distal end of the bolt **106** is screwed into a threaded bore in the proximal end of second resonator **94**. The bolt **106** may be fabricated from steel, titanium, aluminum, or other suitable material. For example, the bolt **106** may be fabricated from Ti-6A1-4V Titanium, or from 4037 low alloy steel.

The piezoelectric elements **100** may be energized in response to the electrical signal supplied from the generator **30** to produce an acoustic standing wave in the acoustic assembly. The electrical signal causes an electromagnetic field across the piezoelectric elements **100**, causing the piezoelectric elements **100** to expand and contract in a continuous manner along the longitudinal axis of the voltage gradient, producing high frequency longitudinal waves of ultrasonic energy. The ultrasonic energy is transmitted through the acoustic assembly to the end effector **180**.

The mounting device **84** of the acoustic assembly has a proximal end, a distal end, and may have a length substantially equal to an integral number of one-half system wavelengths ($n\lambda/2$). The proximal end of the mounting device **84** may be axially aligned and coupled to the distal end of the second resonator **94** by an internal threaded connection near an anti-node. It is also contemplated that the mounting device **84** may be attached to the second resonator **94** by any suitable means, and the second resonator **94** and mounting device **84** may be formed as a single or unitary component.

The mounting device **84** is coupled to the housing **52** of the ultrasonic drive unit **50** near a node. The mounting device **84** may include an integral mounting flange **108** disposed around its periphery. The mounting flange **108** may be disposed in an annular groove **110** formed in the housing **52** of the ultrasonic drive unit **50** to couple the mounting device **84** to the housing **52**. A compliant member or material **112**, such as a pair of silicone rubber O-rings attached by stand-offs, may be placed between the annular groove **110** of the housing **52** and the integral flange **108** of the mounting device **86** to reduce or prevent ultrasonic vibration from being transmitted from the mounting device **84** to the housing **52**.

The mounting device **84** may be secured in a predetermined axial position by a plurality of pins **114**, for example, four. The pins **114** are disposed in a longitudinal direction ninety (90) degrees apart from each other around the outer periphery of the mounting device **84**. The pins **114** are coupled to the housing **52** of the ultrasonic drive unit **50** and are disposed through notches in the acoustic mounting flange **108** of the mounting device **84**. The pins **114** may be fabricated from stainless steel. According to various embodiments, the pins **114** may be formed as integral components of the housing **52**.

The mounting device **84** may be configured to amplify the ultrasonic vibration excursion that is transmitted through the acoustic assembly to the distal end of the end effector **180**. In one embodiment, the mounting device **84** comprises a solid, tapered horn. As ultrasonic energy is transmitted through the mounting device **84**, the velocity of the acoustic

wave transmitted through the mounting device **84** is amplified. It is contemplated that the mounting device **84** be configured as any suitable shape, such as, for example, a stepped horn, a conical horn, an exponential horn, a unitary gain horn, or the like.

The mounting device **84** may be acoustically coupled to the second acoustic portion of the ultrasonic clamp coagulator instrument **120**. The distal end of the mounting device **84** may be coupled to the proximal end of the second acoustic portion by an internal threaded connection near an anti-node, but alternative coupling arrangements can be employed.

FIG. **3** illustrates an exploded view of one embodiment of the surgical instrument shown in FIG. **1**. The proximal end of the ultrasonic clamp coagulator instrument **120** preferably receives and is fitted to the distal end of the ultrasonic drive unit **50** by insertion of the drive unit **50** into the housing **52**, as shown in FIG. **2**. The ultrasonic clamp coagulator instrument **120** may be attached to and removed from the ultrasonic drive unit **50** as a unit. The ultrasonic clamp coagulator **120** may be disposed of after a single use.

The ultrasonic clamp coagulator instrument **120** may include a handle assembly or a housing **130**, which may comprise mating housing portions **131**, **132**, and an elongated or endoscopic portion **150**. When the present apparatus is configured for endoscopic use, the construction can be dimensioned such that portion **150** has an outside diameter of about 5.5 mm. The elongated portion **150** of the ultrasonic clamp coagulator instrument **120** may extend substantially orthogonally from the apparatus housing **130**. The elongated portion **150** can be selectively rotated with respect to the housing **130** as described below. The elongated portion **150** may include an outer tubular member or sheath **160**, an inner tubular actuating member **170**, and the second acoustic portion of the acoustic system in the form of an end effector **180** including a blade **180'**. As will be described, the outer sheath **160**, the actuating member **170**, and the end effector **180** may be joined together for indexed rotation as a unit (together with ultrasonic drive unit **50**) relative to housing **130**.

The proximal end of the end effector **180** of the second acoustic portion may be detachably coupled to the mounting device **84** of the ultrasonic drive unit **50** near an anti-node as described above. The end effector **180** may have a length substantially equal to an integer number of one-half system wavelengths ($n\lambda/2$). The end effector **180** may be fabricated from a solid core shaft constructed out of material which propagates ultrasonic energy efficiently, such as a titanium alloy (e.g., Ti-6A1-4V) or an aluminum alloy. It is contemplated that the end effector **180** can alternatively be fabricated from any other suitable material.

As described, the end effector **180** may include a waveguide **181**. The waveguide **181** may be substantially semi-flexible. It will be recognized that, the waveguide **181** can alternatively be substantially rigid or may comprise a flexible wire. The waveguide **181** may be configured to amplify the mechanical vibrations transmitted through the waveguide to the blade as is well known in the art. The waveguide **181** may further have features to control the gain of the longitudinal vibration along the waveguide **181** and features to tune the waveguide to the resonant frequency of the system.

It will be recognized that the end effector **180** may have any suitable cross-sectional dimension. For example, the end effector **180** may have a substantially uniform cross-section or the end effector **180** may be tapered at various sections or may be tapered along its entire length.

Referring now to FIG. **3**, the waveguide **181** portion of the end effector **180** is shown to comprise a first section **182**, a second section **184**, and a third section **186**. The first section **182** may extend distally from the proximal end of the end effector **180**, and has a substantially continuous cross-section dimension. The first section **182** may include at least one radial hole or aperture **188** extending diametrically therethrough, substantially perpendicular to the axis of the end effector **180**. The aperture **188** may be positioned at a node, but may be otherwise positioned. It will be recognized that the aperture **188** may have any suitable depth and may be any suitable shape. The aperture **188** is configured to receive a connector pin member which connects the wave guide **181**, the tubular actuating member **170**, and the tubular outer sheath **160** together for conjoint, indexed rotation relative to apparatus housing **130**.

The second section **184** of the wave guide **181** extends distally from the first section **182**. The second section **184** preferably also has a substantially continuous cross-section. The diameter of the second section **184** may be smaller than the diameter of the first section **182** and larger than the diameter of the third section **186**. As ultrasonic energy passes from the first section **182** of the end effector **180** into the second section **184**, narrowing of the second section **184** will result in an increased amplitude of the ultrasonic energy passing therethrough.

The third section **186** extends distally from the distal end of the second section **184**. The third section **186** also has a substantially continuous cross-section. The third section **186** also may include small diameter changes along its length. According to various embodiments, the transition from the second section **184** to the third section **186** may be positioned at an anti-node so that the diameter change in the third section does not bring about an increase in the amplitude of vibration.

The third section **186** may have a plurality of grooves or notches (not shown) formed in its outer circumference. The grooves may be located at nodes of the end effector **180** to act as alignment indicators for the installation of a damping sheath (not shown) and stabilizing silicone rings or compliant supports during manufacturing. A seal may be provided at the distal-most node, nearest the blade **180'**, to abate passage of tissue, blood, and other material in the region between the waveguide and actuating member **170**.

The blade **180'** of the end effector **180** may be integral therewith and formed as a single unit. The blade **180'** may alternately be connected by a threaded connection, or by a welded joint. According to various embodiments, the blade **180'** may be mechanically sharp or mechanically blunt. The distal end of the blade **180'** is disposed near an anti-node in order to tune the acoustic assembly to a preferred resonant frequency f_0 when the acoustic assembly is not loaded by tissue. When the transducer assembly is energized, the distal end of the blade **180'** is configured to move longitudinally in the range of, for example, approximately 10-500 microns peak-to-peak, and preferably in the range of about 10 to about 100 microns at a predetermined vibrational frequency f_0.

In accordance with the illustrated embodiment, the blade **180'** may be cylindrical for cooperation with the associated clamping mechanism of the clamp coagulator **120**. The end effector **180** may receive suitable surface treatment, as is known in the art.

FIG. **4** illustrates one embodiment of a clamping mechanism that may be used with the surgical instrument shown in FIG. **1**. The clamping mechanism may be configured for cooperative action with the blade **180'** of the end effector

180. The clamping mechanism includes a pivotally movable clamp arm 190, which is pivotally connected at the distal end thereof to the distal end of outer tubular sheath 160. The clamp arm 190 includes a clamp arm tissue pad 192, preferably formed from TEFLON® or other suitable low-friction material, which is mounted for cooperation with the blade 180', with pivotal movement of the clamp arm 190 positioning the clamp pad 192 in substantially parallel relationship to, and in contact with, the blade 180'. By this construction, tissue to be clamped is grasped between the tissue pad 192 and the blade 180'. The tissue pad 192 may be provided with a sawtooth-like configuration including a plurality of axially spaced, proximally extending gripping teeth 197 to enhance the gripping of tissue in cooperation with the blade 180'.

Pivotal movement of the clamp arm 190 with respect to the blade 180' is effected by the provision of at least one, and preferably a pair of lever portions 193 of the clamp arm 190 at the proximal end thereof. The lever portions 193 are positioned on respective opposite sides of the end effector 180 and blade 180', and are in operative engagement with a drive portion 194 of the reciprocal actuating member 170. Reciprocal movement of the actuating member 170, relative to the outer tubular sheath 160 and the end effector 180, thereby effects pivotal movement of the clamp arm 190 relative to the blade 180'. The lever portions 193 can be respectively positioned in a pair of openings defined by the drive portion 194, or otherwise suitably mechanically coupled therewith, whereby reciprocal movement of the actuating member 170 acts through the drive portion 194 and lever portions 193 to pivot the clamp arm 190.

FIG. 5 illustrates a cut-away view of one embodiment of the surgical instrument shown in FIG. 1, while FIG. 6 illustrates various internal components of one embodiment of the surgical instrument shown in FIG. 1. FIG. 7 illustrates one embodiment of a drive yoke, and FIG. 8 illustrates one embodiment of a drive collar of the surgical instrument shown in FIG. 1. In the embodiment illustrated in FIGS. 3 and 5-8, reciprocal movement of the actuating member 170 is effected by the provision of a drive collar 200 mounted on the proximal end of the actuating member 170 for conjoint rotation. The drive collar 200 may include a pair of diametrically opposed axially extending arms 202 each having a drive lug 204, with the drive lugs 204 being biased by the arms 202 into engagement with suitable openings 206 defined by the proximal portion of tubular actuating member 170. Rotation of the drive collar 200 together with the actuating member 170 is further effected by the provision of a pair of keys 208 diametrically engageable with suitable openings 210 defined by the proximal end of the actuating member 170. A circumferential groove 211 on the actuating member 170 receives an O-ring 211' (FIG. 3) for engagement with the inside surface of outer sheath 160.

Rotation of the actuating member 170 together with the tubular outer sheath 160 and inner end effector 180 is provided by a connector pin 212 extending through these components of the instrument 120. The tubular actuating member 170 defines an elongated slot 214 through which the connector pin 212 extends to accommodate reciprocal movement of the actuating member relative to the outer tubular sheath and the inner waveguide.

A rotation knob 216 mounted on the outer tubular sheath facilitates rotational positioning of the elongated portion 150 with respect to the housing 130 of the clamp coagulator instrument 120. Connector pin 212 preferably joins the knob 216 together with the sheath 160, member 170, and the end effector 180 for rotation as a unit relative to the housing 130. In the embodiment, hub portion 216' of the rotation knob 216 acts to rotatably mount the outer sheath 160, the actuating member 170, and the end effector 180 (as a unit with the knob 216), on the housing 130.

The drive collar 200 provides a portion of the clamp drive mechanism of the instrument 120, which effects pivotal movement of the clamp arm 190 by reciprocation of the actuating member 170. The clamp drive mechanism further includes a drive yoke 220 which is operatively connected with an operating lever 222, with the operating lever thus interconnected with the reciprocal actuating member 170 via drive yoke 220 and drive collar 200. The operating lever 222 is pivotally connected to the housing 130 of the apparatus (by a pivot mount 223) for cooperation in a scissors-like fashion with a handgrip portion 224 of the housing. Movement of the lever 222 toward the handgrip portion 224 translates the actuating member 170 proximally, thereby pivoting the clamp arm 190 toward the blade 180'.

Operative connection of the drive yoke 220 with the operating lever 222 is provided by a spring 226, preferably comprising a compression coil spring 226. The spring 226 fits within a spring slot 228 defined by the drive yoke 220, which in turn is positioned between a pair of spring retainer flanges 230 of the operating lever 222. The drive yoke 220 is pivotally movable with respect to the spring flanges 230 (about pivot mount 223 of housing 130) in opposition to the compression coil spring, which bears against the surfaces of the spring slots defined by each of the spring flanges 230. In this manner, the force which can be applied to the actuating member 170, by pivotal movement of the operating lever 222 acting through the drive yoke 220 and the drive collar 200, is limited by the force with which the spring 226 bears against the spring flanges 230. Application of excessive force results in pivotal displacement of the drive yoke 220 relative to the spring flanges 230 of the operating lever 222 in opposition to spring 226. Stop portions of the housing 130 limit the travel of the operating lever 222 to prevent excessive compression of spring 226. In various embodiments, the force applied to the actuating member 170 may be limited by one or more springs (not shown) operatively positioned between the drive collar 200 and the member 170. For example, one or more cylindrical springs, such as a wave springs, may be used. An example embodiment utilizing a wave spring in this manner is described in U.S. Pat. No. 6,458,142, which is incorporated herein by reference.

Indexed rotational positioning of the elongated portion 150 of the present clamp coagulator instrument 120 may be provided by the provision of a detent mechanism incorporated into the clamp drive mechanism of the instrument 120. Specifically, the drive collar 200 may include a pair of axially spaced apart drive flanges 232. A detent-receiving surface may be provided between the drive flanges 232, and may define a plurality of circumferentially spaced teeth 234. The teeth 234 may define detent-receiving depressions generally about the periphery of the drive collar 200. In the embodiment illustrated in FIG. 7, twelve (12) of the teeth 234 are provided, thereby providing indexed positioning of the elongated portion 150 of the apparatus at 30° intervals relative to the housing 130 of the apparatus.

Indexed rotational movement may be further achieved by the provision of at least one, and preferably a pair, of diametrically opposed detents 236 respectively provided on cantilevered yoke arms 238 of the drive yoke 220. By this arrangement, the yoke arms 238 are positioned between the drive flanges 232 for engagement with the confronting surfaces thereof, and bias the detents 236 into engagement with the drive collar 200. Indexed relative rotation is thus

achieved, with the detents **236** of the yoke arms **238** cooperating with the drive flanges **238** for effecting reciprocation of the actuating member **170**. According to various embodiments, the drive yoke **220** may be formed from suitable polymeric material, with the biasing force created by the yoke arms **238** acting on the detents **236** thereof cooperating with the radial depressions defined by the drive collar to resist relative rotational torque less than about 5 to 20 inch-ounces. Accordingly, the elongated portion **150** of the clamp coagulator instrument **120** is maintained in any of its selected indexed rotational positions, relative to the housing **130**, unless a torque is applied (such as by the rotation knob **216**) exceeding this predetermined torque level. A snap-like indexing action is thus provided.

Rotation of the elongated proportion **150** of the present clamp coagulator instrument **120** may be effected together with relative rotational movement of ultrasonic drive unit **50** with respect to housing **130**. In order to join the elongated portion **150** to the ultrasonic drive unit **50** in ultrasonic-transmitting relationship, the proximal portion of the outer tubular sheath **160** may be provided with a pair of wrench flats **240** (FIG. **3**). The wrench flats allow torque to be applied by a suitable torque wrench or the like to thereby permit the end effector **180** to be joined to the ultrasonic drive unit **50**. The ultrasonic drive unit **50**, as well as the elongated portion **150**, are thus rotatable, as a unit, by suitable manipulation of the rotation knob **216**, relative to the housing **130** of the apparatus. The interior of housing **130** is dimensioned to accommodate such relative rotation of the drive unit **50**.

FIG. **9** illustrates one embodiment of a surgical system **250** including a surgical instrument **251** having single element end effector **256**. The system **250** may include a transducer assembly **252** coupled to the end effector **256** and a sheath **254** positioned around the proximal portions of the end effector **256** as shown. The transducer assembly **252** and end effector **256** may operate in a manner similar to that of the transducer assembly **50** and end effector **180** described above to produce ultrasonic energy that may be transmitted to tissue via a blade **256'**.

FIG. **10** illustrates a block diagram of one embodiment of a surgical device **1000**, which may be configured with temperature feedback functionality. For example, the control circuit **1002** may adjust a current amplitude of an electrical signal provided by the generator **1004** to the transducer **1006** in response to changes in a vibration frequency of the end effector **1008**. According to various embodiments, when the vibration frequency of the end effector **1008** drops, the amplitude of the electrical signal may be reduced. This may allow the surgical device **1000** to maintain the end effector **1008** at a relatively constant temperature and, thus give the device **1000** more uniform performance.

During surgical procedures, the end effector **1008** may be brought into contact with tissue and vibrated to cut and/or coagulate the tissue, as described above. When this occurs, friction between the end effector **1008** and the tissue may cause the temperature of the end effector **1008** to rise. As the temperature of the end effector **1008** rises, its material properties may change, causing changes to the device **1000** as a whole. For example, as the temperature of the end effector **1008** rises, the relationship between the displacement of the end effector **1008** and the current amplitude of the electrical signal may change such that the displacement of the end effector **1008** increases without a corresponding increase in the current amplitude. Also, as the temperature of the end effector **1008** rises, the resonant vibration frequency of the end effector **1008** may be reduced. For example, the changed material properties of the end effector **1008** may reduce the resonant frequency of the device **1000**. As a result, the generator **1004** may reduce the frequency of the electrical drive signal bringing about a parallel reduction in the driven vibration frequency of the end effector **1008**.

The control circuit **1002** may monitor the electrical signal provided by the generator **1004**. As described, a decrease in the frequency of the electrical signal may indicate an increase in the temperature of the end effector **1008** as well as an increase in its displacement. When the control circuit **1002** senses a decrease in the frequency of the electrical signal it may command the generator **1004** to reduce the current amplitude of the electrical signal. The current amplitude of the electrical signal may be reduced by an amount suitable to keep the frequency of the end effector **1008** substantially constant resulting in a substantially constant temperature of the end effector **1008**. The amount of current amplitude change necessary to compensate for a given frequency change may be determined by any suitable experimental or theoretical method.

It will be appreciated that the device **1000** may be physically embodied as any suitable ultrasonic device or system including, for example, the systems **10** and **250** described above. The control circuit **1002** may be embodied as any suitable analog or digital circuit. For example, the control circuit **1002** may comprise a processor, for example, a digital signal processor (DSP).

In addition to, or instead of the temperature feedback functionality described above, one embodiment of the device **1000** shown in FIG. **10** may be configured to detect cavitation, wherein the acoustic cavitation signal is transferred from the tissue to the end effector **1008**. This may provide the clinician with information regarding the state of the tissue. For example, before the tissue is desiccated, substantially all of the water present in the tissue may be removed, either by evaporation or boiling. As water is evaporated or boiled, it may generate cavitations in the tissue. Detecting the presence of these cavitations may allow the device **1000** to give the clinician an indication that the tissue is, or is about to be, desiccated. Other tissue transitions occurring during cutting and/or coagulation may be indicated by various other cavitations.

Tissue cavitations originating from tissue in contact with the end effector **1008** (and/or from fluid included within the tissue) may affect the vibration of the end effector **1008**, and accordingly the electrical signal between the generator **1004** and the transducer **1006**. As described above, the piezoelectric elements (not shown) may generate motion in response to an electrical charge. Also, piezoelectric elements may work in reverse and generate and/or modify an electrical charge in response to motion. Accordingly, tissue cavitations transferred to the end effector **1008** may be, in turn, transferred to the piezoelectric elements of the transducer **1006**. This may cause the piezoelectric elements to generate charges that modify the electrical signal between the generator **1004** and the transducer **1006** in a manner proportional to the tissue cavitations. Isolating the portion of the electrical signal due to the tissue cavitations may indicate the presence of tissue cavitations, as well as their dominant frequency/frequencies, and other information.

The portion of the electrical signal due to tissue cavitation may be isolated in any suitable way. For example, the control circuit **1002** may include a filter circuit (not shown) to filter the drive frequency and any harmonics thereof from the electrical signal. The remaining components of the electrical signal may be due to tissue cavitation. The filter circuit may comprise any suitable analog or digital filter.

Many tissue cavitations are of a relatively short duration, and therefore have a relatively wide frequency content. Accordingly, the tissue cavitations may not be apparent at any distinct frequencies and may instead serve to excite the end effector **1008** at its resonant frequency (e.g., the vibration frequency) and the harmonics thereof. To handle this scenario, the control circuit **1002** may include a processor or other functionality to compare the electrical signal to a comparison electrical signal measured when the end effector **1008** is unloaded, or not in contact with tissue. Differences between the measured electrical signal and the comparison electrical signal may indicate the presence of tissue cavitations. When the control circuit **1002** senses the presence of tissue cavitations, it may communicate this to the clinician any suitable method including, for example, by using a light, a display and/or an audible signal.

FIG. **11** shows a graph **1100** illustrating results of an example test of one embodiment of a surgical device. In the example test, external cavitations are identified by analyzing the frequency content of an electrical signal between a transducer and an end effector. In the test, an LCS14C end effector was used in conjunction with a HP054 transducer and a GEN 300 generator operated at a nominal drive frequency of 55.5 kHz. All of these components are available from Ethicon Endo Surgery, Inc. A control trial was performed by energizing the end effector in air at a level **5** power setting for a period of 100 milliseconds. During this time, the electrical signal between the transducer and generator was monitored with an AGILENT Oscilloscope Model 5483D. For each experimental trial, the end effector was placed in a plastic beaker filled with 400 cc of fresh tap water. The end effector was then energized at a given power level for a period of 100 milliseconds while the electrical signal between the transducer and generator was monitored with the oscilloscope. Three experimental trials were run at generator settings of 1, 3 and 5 respectively.

The graph **1100** illustrates the amplitudes of low-Q peaks in the electrical signal observed during the control and experimental trials at the drive frequency and at two harmonics of the drive frequency. Line **1102** illustrates the drive frequency of 55.5 kHz, line **1104** illustrates a first harmonic at 45 kHz, and line **1106** illustrates a second harmonic at 63 kHz. It can be seen that the amplitude of the low-Q peak at the drive frequency was markedly higher during the experimental trials than during the control trial. Likewise, the amplitude of the low-Q peaks at the harmonics was higher during the experimental trials. It is believed that these increased amplitudes at the drive frequency **1102** and the harmonics **1104**, **1106** were due to cavitations caused when dissolved gas in the tap water was released by the vibration of the end effector. In support of this conclusion, it is noted that when the tap water was not changed between trials, the low-Q peaks were significantly smaller, suggesting that all of the dissolved gas had been released. When the end effector encounters tissue cavitations, similar effects would be apparent in the low-Q peaks at the drive and harmonic frequencies of the device.

In addition to, or instead of the functionality described above, the device **1000** shown in FIG. **10** may have functionality for monitoring changes in the frequency of the end effector **1008**. For example, the control circuit **1002** may monitor the vibration frequency of the end effector to detect changes. Changes in end effector frequency may indicate changes in tissue that is in contact with the end effector. FIG. **12** shows a chart **1200** illustrating a relationship between end effector frequency **1202** and end effector temperature **1204** over the coagulation and cutting process. The horizontal axis **1201** represents time while the vertical axis **1203** represents temperature with respect to the curve **1204** and end effector vibration frequency with respect to the curve **1202**. The vertical line **1206** represents the approximate beginning of tissue coagulation (e.g., the denaturing of collagen described above). Vertical line **1208** represents the approximate beginning of desiccation and incipient transection.

Over the course of the cutting/coagulation process shown in chart **1200**, the temperature curve **1204** increases. Prior to the beginning of coagulation **1206**, the temperature curve **1204** increases sharply. Between coagulation **1206** and desiccation **1208**, the increase in the slope of the temperature versus time curve **1204** is reduced. After desiccation **1208**, the temperature curve **1204** again begins to increase more rapidly. The end effector frequency curve **1202** may mirror the temperature curve **1204**. For example, the frequency curve **1202** may decrease rapidly prior to the beginning of coagulation **1206**. At the beginning of coagulation **1206**, the frequency curve **1202** continues to decrease, but does so less rapidly, demonstrating a knee feature **1210**. At around the onset of desiccation **1208**, the frequency curve **1208** may begin to decrease more rapidly.

According to various embodiments, the control circuit **1002** may be programmed to recognize the changes in the rate of decrease in the frequency curve **1202** to derive an indication of when tissue has begun to coagulate, and when it has begun desiccation. In one embodiment, the control circuit **1002** may monitor the vibration frequency of the end effector **1008** by monitoring the frequency of the electrical signal between the generator **1004** and transducer **1006**. It will be appreciated that these two frequencies may be the same. When the control circuit **1002** senses that the rate of decrease of the end effector frequency has declined (e.g., the curve **1202** has reached the knee feature **1210**), the control circuit **1002** may generate an indication that coagulation has begun. When the control circuit **1002** senses that the rate of decrease of the end effector frequency has again increased, it may indicate the beginning of desiccation. The various indications may be communicated to the clinician by the device **1000** according to any suitable method including, for example, a light, a display and an audible signal. According to various embodiments, the control circuit **1002** may de-energize the end effector **1008**, or reduce its amplitude of vibration, in response to a transition to coagulation or to desiccation. This may allow the clinician to inspect the tissue before coagulation and/or desiccation to ensure that the procedure is proceeding satisfactorily.

According to various embodiments, the device **1000** of FIG. **10** may combine frequency change functionality with tissue cavitation sensing functionality to indicate the state of tissue in contact with the end effector **1008**. For example, although the frequency curve **1202** shown in FIG. **12** illustrates a knee feature **1210** at the onset of coagulation **1206**, its rate of frequency change may transition more gradually at the onset of desiccation **1208**. Accordingly, it may be difficult to accurately identify the onset of desiccation **1208** by monitoring the end effector frequency alone. Tissue cavitations, on the other hand, are most common at about the onset of desiccation **1208**. For example, as water is evacuated from the tissue, it may boil violently, causing cavitations. Accordingly, the control circuit **1002** may be configured to identify the onset of coagulation **1206** by identifying the knee **1210** in the end effector frequency curve **1202**, as described above. Also, the control circuit **1002** may be configured to identify the onset of desiccation **1208** by identifying tissue cavitations, for example, in conjunction

with an increase in the rate of reduction of the end effector frequency curve **1202**. Again, the various indications may be communicated to the clinician by the device **1000** according to any suitable method including, for example, a light, a display and an audible signal. Also, the device **1000** may be de-energized, or the vibration frequency of the end effector **1008** reduced, upon a transition to coagulation or desiccation, as described above.

FIG. **13** illustrates a block diagram of one embodiment of a surgical device **1300** configured to derive end effector feedback considering a coefficient of collagen denaturation (CCD). The CCD may represent an amount of friction between the end effector **1308** and a portion of tissue (not shown). Analysis of a CCD curve taken over the course of a cutting and/or coagulation procedure may provide information about the progress of the cutting and coagulation as well as information about the tissue portion including, for example, its thickness and outside diameter.

According to various embodiments, the CCD may be calculated as a function of variables, for example, including: (i) power provided to the end effector **1308**; (ii) the vibration frequency of the end effector **1308**; (iii) the displacement of the end effector **1308** over a cycle; and (iv) a clamp force applied to the region of tissue between the clamping mechanism **1310** and the end effector. The clamping mechanism **1310** itself may be any suitable mechanism for clamping or otherwise exerting a force on the tissue region against the end effector. According to various embodiments, the clamping mechanism **1310** may be similar to the clamping mechanism **190** described above. Values for the above variables over time may be found by the control circuit **1302** of the device **1300**. For example, the power provided to the end effector **1308** may be found by considering the electrical signal between the generator **1304** and the transducer **1306** while the end effector **1308** is under load (e.g., in contact with the region of tissue). The displacement per cycle of the end effector **1308** may be a function of the current amplitude of the electrical signal. Also, as described above, the vibration frequency of the end effector **1308** may be substantially similar to that of the electrical signal.

The clamp force of the end effector **1308** and clamping mechanism **1310** may be found according to any suitable method. For example, according to various embodiments, the clamping mechanism **1310** may be driven by an electric motor. For example, referring to the embodiment shown in FIG. **2**, the reciprocal actuating member **170** may be translated distally and proximally by the motor **1312**. In this embodiment, the clamping force between the clamping mechanism **1310** and the end effector **1308** may be derived from a drive electrical signal provided to the motor **1312**. For example, the current amplitude of the drive electrical signal may indicate the clamping force. According to various embodiments, the clamp force may be derived from a sensor **1314** in communication with the control circuit **1302**. The sensor may be placed at any suitable location in communication with the end effector **1308**, clamping mechanism **1310** and/or a portion of the device handpiece (not shown in FIG. **13**). The embodiment shown in FIG. **4** illustrates one example of a sensor **1316** positioned between the clamp arm tissue pad **192** and clamp arm **190**. Also, the embodiment shown in FIG. **2** illustrates a sensor **1318** positioned between a portion of the operating lever **222** and drive collar **200**. In one embodiment, the clamp force may be considered a constant and factored into the CCD calculations as such.

The device **1300** may utilize the CCD curve to sense when the portion of tissue enters the coagulation and desiccation stages. FIG. **14** shows a graph illustrating a CCD curve **1402** over a full coagulating and cutting transaction. The CCD curve **1402** was derived with an ultrasonic instrument having a solid core end effector powered by a GEN03 generator device available from Ethicon Endo Surgery, Inc. The power of the generator was set to level three (3); the end effector **1408** displacement was set to 55 microns; the end effector vibration frequency was configured at 55.5 kHz; and a clamping force of 2 pounds was utilized. The curve **1402** may be divided into three regions. A first region **1408** may correspond to times before the onset of coagulation **1404** and may have a substantially negative slope. A second region **1410** may correspond to times between the onset of coagulation **1404** and the onset of desiccation **1406** and may have a substantially neutral slope. A third region **1412** may correspond to times after the onset of desiccation **1406** and may have a substantially positive slope. According to various embodiments, the control circuit may monitor the slope of the CCD curve **1402** to determine the state of the tissue portion. Transitions to coagulation or to desiccation may be indicated to the clinician according to any suitable method including, for example, a light, a display and/or an audible signal. Also, as described, the control circuit **1302** may de-energize the end effector **1308** in response to a transition to coagulation or to desiccation.

The CCD curve **1402** also may be utilized by the control circuit **1302** to determine other features of the tissue portion including, for example, its outside diameter and thickness. It will be appreciated that the tissue portion may be a solid portion of tissue, or may define a lumen (e.g., an artery, vein or other tubular tissue time). FIG. **15** shows a graph illustrating a coefficient of collagen denaturation curve **1502**. The curve **1502** was derived over the coagulation and desiccation of a Carotid artery utilizing an ultrasonic instrument having a solid core end effector powered by a GEN03 generator device. The power of the generator was set to level five (5). The end effector **1408** displacement was set to 55 microns; the end effector vibration frequency was configured at 55.5 kHz; and a clamping force of 2 pounds was utilized. The CCD curve **1502** has been broken into nine regions **1504**, **1506**, **1508**, **1510**, **1512**, **1514**, **1516**, **1518** and **1520** having a substantially constant slope.

Various properties of each of the nine regions of the CCD curve **1402** may correlate to properties of the tissue portion such as the outer diameter and thickness. In one example experiment, fourteen carotid arteries of various diameters were coagulated and cut with an ultrasonic instrument having a solid core end effector powered by a GEN03 generator device. Table 1 below shows the Outside Diameter and Wall Thickness of the carotid arteries as well as the Clamp Force and Power Level used. The Polynomial Fit column lists the exponent of the polynomial fit to the first region **1504** of the CCD curve for each trial. The Normalized CCD value shows the CCD value for each trial normalized by dividing each individual CCD value by the CCD value at the end of the first region **1504**.

TABLE 1

Trial	Clamp Force	Power Level	Outside Diameter (in.)	Wall Thickness	Poly-nomial Fit	Normalized CCD Value
1	0.4	3	0.169	0.042	.0181	1.2826
2	1	3	0.169	0.042	0.254	*
3	0.4	5	0.117	0.04	0.227	*
4	1	5	0.117	0.04	0.251	*
5	0.4	4	0.146	0.042	0.251	1.16738

TABLE 1-continued

Trial	Clamp Force	Power Level	Outside Diameter (in.)	Wall Thickness	Poly-nomial Fit	Normalized CCD Value
6	1	4	0.146	0.042	0.361	1.47
7	0.4	4	0.136	0.05	0.266	1.14
8	1	4	0.136	0.05	1.231	1.23
9	0.7	3	0.094	0.045	1.765	1.05
10	0.7	5	0.094	0.045	0.744	1.35
11	0.7	3	0.156	0.045	0.15	1.1
12	0.7	5	0.156	0.045	0.214	1.49
13	0.7	4	0.119	0.035	0.791	1.27
14	0.7	4	0.119	0.035	0.295	1.23

FIG. **16** shows a series of curves **1602**, **1604**, **1606**, **1608** illustrating relationships between the normalized value of the first point of the first region of the CCD curve clamp force, power level, outside diameter and wall thickness for the trials shown in Table 1. The degree of the slope of the curves **1602**, **1604**, **1606**, **1608** may indicate the degree of correlation between the corresponding variable and the normalized value of the first point of the first region of the CCD curve. It can be seen that all of the curves **1602**, **1604**, **1606** and **1608** have non-zero slopes, and therefore all of their corresponding variables are correlated to the CCD curve. A mathematical model, such as a quadratic model, may be fit to the results of trials, such as those shown in Table 1, to derive one or more equations relating the normalized value of the first point of the first region of the CCD curve, the clamp force, the power level, outside diameter and wall thickness.

Referring back to the embodiment shown in FIG. **13**, the control circuit **1302** may monitor a CCD curve generated as the device **1300** coagulates and/or cuts the tissue portion. Upon identifying a region of the CCD curve having a substantially similar slope, the control circuit **1302** may derive a property describing the region including, for example, a slope of the region, a normalized value of the curve in the region and/or a length of the first region. The control circuit **1302** may then derive a property of the tissue portion including, for example an outside diameter of the tissue portion or a thickness of the tissue portion. The tissue properties may be derived according to any suitable method. For example, mathematical models relating region properties to tissue properties may be developed, for example, as described above. The control circuit **1302** may utilize a predetermined mathematical model to relate the region property and tissue property. Also, according to various embodiments, look-up tables may be generated relating region properties to tissue properties.

FIG. **17** illustrates one embodiment of an end effector **1700** for a surgical device including radial mode transducers **1702**, **1704**, **1706**. When excited by an electrical signal (e.g., from a generator) the radial mode transducers **1702**, **1704**, **1706** may generate ultrasonic vibrations perpendicular to a longitudinal axis **1710**. The ultrasonic vibrations may have anti-nodes at the radial surfaces of the transducers **1702**, **1704**, **1706**. As a result, the entire radial surface of the end effector **1700** may be active for coagulating and cutting tissue. A central member **1708** may extend along the longitudinal axis **1710** and may serve as an electrode for some or all of the radial mode transducer **1702**, **1704**, **1706**. Additionally the outer radial surface of the radial mode transducers **1702**, **1704**, **1706** may be coated with an electrically conductive substance or alternatively may be enclosed in a metal tubular sheath, either of which may serve as an electrode. Although multiple transducers **1702**, **1704**, **1706** are shown, it will appreciated that some embodiments may include only one radial mode transducer.

FIG. **18** illustrates one embodiment of the end effector **1700** of FIG. **17** installed on a surgical instrument **1800** including a clamp arm **1802**. Additional radial mode transducers **1701** and **1703** are shown, although it will be appreciated that any suitable number of transducers may be used. The clamp arm **1802** may be pivotable toward the end effector **1700** similar to the way that clamp arm **190** is pivotable toward end effector **180** in the embodiment shown in FIG. **4**. According to various embodiments, the central member **1708** of the end effector **1700** may be flexible. This may allow the various radial mode transducers **1702**, **1704**, **1706** to flex relative to each other. FIG. **19** illustrates one embodiment of the end effector **1700** of FIG. **17** where the central member **1708** is flexible. The flexibility of the central member **1708** may allow the different radial mode transducers, here **1706** and **1704**, to flex relative to one another leading to a flexible and articulatable end effector **1700**. Articulation of the end effector **1700** may be brought about in any suitable manner. For instance, the flexible central member **1708** may define a central lumen (not shown). Metal wires (not shown) may run within the central member **1708** on opposing sides of the central lumen. An articulation knob or other articulate implement near a handle portion of the instrument may be used to retract one of the metal wires. When a metal wire is retracted, it may cause the flexible central member **1708**, and therefore the end effector **1700** to articulate in the direction of the retracted wire. For example, if a wire on the right side of the central member **1708** is retracted, then the end effector **1700** may articulate to the right. It will be appreciated that this is but one example of an articulation mechanism and that any suitable articulation method may be used.

FIGS. **20-21** illustrate one embodiment of the end effector **1700** of FIG. **17** including a transducer **2002** defining a concavity **2004**. The transducer **2002** may utilize the concavity **2004** to direct ultrasonic energy to tissue that is not in direct physical contact with the transducer **2002** or the end effector **1700**. For example, the concavity of the transducer **2002** may serve to focus ultrasonic energy to points **2006**. According to various embodiments, the concavity **2004** may extend radially around the transducer **2002**, as shown in the embodiment of FIG. **21**. Accordingly, the focal point **2006** extends radially around the transducer **2002** forming a toroid.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device may be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular elements, and subsequent reassembly. In particular, the device may be disassembled, and any number of particular elements or components of the device may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular components, the device may be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device may utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the various embodiments described herein will be processed before surgery. First, a new or used instrument

is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

It is preferred that the device is sterilized prior to surgery. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

Although various embodiments have been described herein, many modifications and variations to those embodiments may be implemented. For example, different types of end effectors may be employed. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

What is claimed is:

1. An ultrasonic surgical instrument, the instrument comprising:

a transducer positioned along a longitudinal axis;

an end effector coupled to the transducer and extending away from the transducer along the longitudinal axis;

a control circuit, wherein the control circuit is configured to:

provide a drive signal to the transducer to cause the transducer to provide vibrations along the longitudinal axis;

detect a change in a vibration frequency of the end effector based at least in part on a change in a frequency of the drive signal;

correlate the change in vibration frequency of the end effector to a tissue condition of tissue in contact with the end effector; and

modify the drive signal in response to the tissue condition.

2. The ultrasonic surgical instrument of claim **1**, wherein the change in the vibration frequency of the end effector comprises a reduction in a rate of decrease of the vibration frequency of the end effector, and wherein the tissue condition is an onset of tissue coagulation.

3. The ultrasonic surgical instrument of claim **2**, wherein the control circuit is further configured to detect a second change in the vibration frequency of the end effector after the change in the vibration frequency of the end effector, wherein the second change in the vibration frequency of the end effector comprises an increase in the rate of decrease of the vibration frequency of the end effector after the reduction in the rate of decrease of the vibration frequency of the end effector, and wherein the tissue condition is an onset of tissue desiccation.

4. The ultrasonic surgical instrument of claim **1**, wherein the change in the vibration frequency of the end effector comprises an increase in a rate of decrease of a vibration frequency of the end effector, and wherein the tissue condition is an onset of tissue desiccation.

5. The ultrasonic surgical instrument of claim **1**, wherein the tissue condition is an onset of tissue coagulation, and wherein modifying the drive signal in response to the tissue condition comprises making at least one modification selected from the group consisting of de-energizing the end effector and reducing an amplitude of vibration of the end effector.

6. The ultrasonic surgical instrument of claim **1**, wherein the tissue condition is an onset of tissue desiccation, and wherein detecting the change in the vibration frequency of the end effector comprises-isolating a frequency component of the drive signal attributable to a cavitation of the end effector caused by the tissue.

7. The ultrasonic surgical instrument of claim **1**, wherein the control circuit is further configured to:

detect a power provided to the end effector;

correlate the power provided to the end effector to a second tissue condition; and

modify the drive signal in response to the second tissue condition.

8. The ultrasonic surgical instrument of claim **7**, wherein detecting the power provided to the end effector comprises monitoring the drive signal when the end effector is under load.

9. The ultrasonic surgical instrument of claim **1**, wherein the control circuit is further configured to detect a displacement of the end effector, based at least in part on the drive signal.

10. The ultrasonic surgical instrument of claim **9**, wherein detecting the displacement of the end effector comprises monitoring a current of the drive signal.

11. The ultrasonic surgical instrument of claim **1**, further comprising a clamp arm pivotable relative to the end effector, wherein the control circuit is further configured to detect a clamp force applied between the clamp arm and the end effector.

12. The ultrasonic surgical instrument of claim **1**, wherein the control circuit is further configured to receive a model relating changes in vibration frequency of the end effector to tissue conditions and wherein correlating the change in vibration frequency of the end effector to the tissue condition comprises applying the model.

13. The ultrasonic surgical instrument of claim **1**, wherein the control circuit is further configured to generate a signal indicating the tissue condition.

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